

**The Medicare Prescription Drug, Improvement,
And Modernization Act of 2003:
POOR Medicine or Just What the Doctor Ordered?**

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I. INTRODUCTION

The average Medicare recipient spends more on prescription drugs than on doctor visits, medical supplies, and vision services combined.¹ Yet, current estimates indicate that at any one time, over one-third of Medicare beneficiaries lack any prescription drug insurance coverage.² To address Medicare-eligible seniors' prescription drug insurance needs, Congress enacted and President George W. Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), designed in part to provide comprehensive outpatient prescription drug benefits to Medicare-eligible seniors.³

In its current form, however, this law is not a comprehensive prescription drug plan that effectively assists all Medicare-eligible seniors with prescription drug costs.⁴ In fact, although the MMA is a first step toward providing Medicare-eligible seniors with affordable prescription

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¹ John Rother, *Advocating for a Medicare Prescription Drug Benefit*, 3 YALE J. HEALTH POL'Y L. & ETHICS, 279, 280 (2003).

² *Medicare: Financial Outlook Poses Challenges for Sustaining Program and Adding Drug Coverage Before the House Comm. on Ways and Means*, 107th Cong. 1 (2002) (statement of David M. Walker, Comptroller of the United States), <http://www.gao.gov/new.items/d02643t.pdf>.

³ Marilyn Moon, *How Beneficiaries Fare Under the New Medicare Drug Bill 1*, The Commonwealth Fund Issue Brief (June 2004), <http://www.cmwf.org>. In addition to providing Medicare-eligible seniors with outpatient prescription drug coverage, the Act also provides increased payments to both Medicare managed care plans and Medicare fee-for-service providers. Thomas Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, THE MILLBANK Q. No. 2, 283, 317 (2004). Consideration of MMA provisions other than the prescription drug benefit is beyond the scope of this article.

⁴ Jim Mays et al., *Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006* vii, The Henry R. Kaiser Family Foundation (Nov. 2004), <http://www.kff.org>.



drug insurance, the benefit does not provide meaningful prescription drug coverage for those beneficiaries who are ineligible for the plan's low-income subsidies.⁵ Furthermore, the benefit does not effectively assist those with moderate out-of-pocket prescription drug spending.⁶ To provide all Medicare-eligible seniors with more comprehensive, affordable prescription drug coverage, Congress must enact additional legislation.

This comment provides an in-depth analysis of the MMA as it relates to the new Medicare prescription drug benefit. Specifically, Part II addresses the historical development of Medicare, which for almost forty years lacked a prescription drug benefit, and the events that drove Congress and President Bush to enact a new prescription drug benefit. Part II also details the new drug benefit, including the prescription drug discount cards issued in 2004 and the specific prescription drug benefits seniors are scheduled to receive under the legislation that takes effect in 2006.

Part III addresses the law's problems and asserts that the MMA outpatient prescription drug program fails to provide many Medicare beneficiaries with meaningful, affordable prescription drug coverage. To meet its goal of providing all Medicare beneficiaries with comprehensive access to affordable prescription drugs while ensuring that the costs to both beneficiaries and the United States government are reasonable, Congress should enact additional legislation. Part IV addresses legislative proposals, which, if enacted, would provide more comprehensive prescription drug benefits to all Medicare recipients while keeping beneficiaries' premiums reasonable and the Medicare program solvent.

II. BACKGROUND

A. THE HISTORICAL STRUGGLE FOR A MEDICARE PRESCRIPTION DRUG BENEFIT.

Enacting a Medicare outpatient prescription drug benefit was a lengthy and controversial process.⁷ The drug benefit's long history and development illuminates both why Medicare beneficiaries needed a prescription drug benefit and the enormous degree of political compromise

⁵ *Id.*

⁶ *Id.*

⁷ See generally, Oliver et al., *supra* note 3. In fact, enacting an outpatient prescription drug benefit took almost forty years. *Id.* at 285.

that was required to enact the MMA.⁸ Additionally, the benefit's history and development suggests that even though the benefit is not a comprehensive prescription drug plan for all Medicare beneficiaries, the benefit's very existence is quite an achievement.

Between 1945 and 1948, President Harry Truman first introduced into the political arena the concept of a nationalized health insurance plan for seniors.⁹ The American Medical Association ("AMA") immediately termed President Truman's nationalized health insurance plan "socialized medicine" and launched a well-funded attack to defeat it.¹⁰ After this defeat, Congress and the President did not again consider nationalized health insurance until the 1960's.¹¹

In 1965, well aware of the AMA's defeat of President Truman's proposal, President Lyndon Johnson introduced to Congress a very limited nationalized health insurance plan for seniors that covered only the costs of hospitalization.¹² Subsequently, policymakers amended the plan to include the cost of outpatient prescription drugs.¹³ However, because financial analysts claimed that "unpredictable and potentially high costs" would accompany a Medicare prescription drug benefit, Congress abandoned the outpatient prescription drug proposal.¹⁴ Consequently, from its outset, because Medicare lacked an outpatient prescription drug

⁸ Oliver et al., *supra* note 3, at 283. Policymakers seeking to expand the government's role in providing Medicare coverage negotiated with policymakers seeking an increased role for private health care providers. *Id.* at 332.

⁹ See President Harry Truman, Special Message to the Congress Presenting a 21-Point Plan for Reconversion Period (Sept. 6, 1945), <http://www.trumanlibrary.org/publicpapers>; Harry Truman, Annual Budget Message to the Congress, Fiscal Year 1949 (Jan. 12, 1948), <http://www.trumanlibrary.org/publicpapers>.

¹⁰ *PBS Healthcare Crisis: Healthcare Timeline*, <http://www.pbs.org/healthcarecrisis/history.htm>; *American Medical Association History 1941-1960*, <http://www.ama-assn.org>.

¹¹ Oliver et al., *supra* note 3, at 290.

¹² Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended in scattered sections of 26 and 42 U.S.C.). This proposal developed into Medicare, with Part A providing hospital insurance and Part B providing supplementary medical insurance and very limited prescription drug coverage. *Id.*

¹³ Oliver et al., *supra* note 3, at 291.

¹⁴ *Id.*

benefit, Medicare provided outpatient prescription drug coverage for only a very limited number of drugs actually dispensed to beneficiaries in a physician's office.¹⁵

Soon after implementation, the Medicare program encountered unexpected increases in hospital and physician services spending.¹⁶ Due to this rapid cost escalation, President Johnson again refused to support outpatient prescription drug coverage,¹⁷ even though seniors' prescription drug costs and usage were growing rapidly.¹⁸ Moreover, in the late 1970's, Watergate, the energy crisis, a weak economy, and rising inflation caused President Carter to avoid implementing costly new initiatives, including a drug benefit.¹⁹ After President Carter refused to enact a Medicare drug benefit, an outpatient prescription drug benefit was not seriously considered for ten subsequent years.²⁰

In 1988, President Ronald Reagan and Congress implemented the Medicare Catastrophic Coverage Act (hereinafter "MCCA"),²¹ which was originally intended to cap beneficiaries' total out-of-pocket Medicare expenses and modestly expand Medicare Part B coverage.²² To garner bipartisan support for the bill, legislators added many Medicare related provisions, including an outpatient prescription drug benefit.²³ In June 1988, both houses passed MCCA, which included a scaled back prescription drug benefit, and President Reagan signed it into law.²⁴

¹⁵ Social Security Amendments of 1965.

¹⁶ *PBS Healthcare Crisis: Healthcare Timeline*, <http://www.pbs.org/healthcarecrisis/history.htm>.

¹⁷ Oliver et al., *supra* note 3, at 293.

¹⁸ *Id.* at 294.

¹⁹ *Id.* at 296.

²⁰ *Id.*

²¹ Medicare Catastrophic Coverage Act, 42 U.S.C. § 1395 (repealed 1989).

²² *Id.*

²³ *Id.*

²⁴ Bill Summary and Status for the 100th Congress, H.R. 2470 (1987), <http://thomas.loc.gov>. (follow "Search Bills and Resolutions" hyperlink under "Legislation," then search in "Summary and Status Information about Bills and Resolutions" for Bill Number H.R. 2470, 100th Congress) (last visited Oct.14, 2005). The bill passed both houses with large bipartisan majorities. *Id.* MCCA's prescription drug benefit required all Medicare eligible seniors' enrollment,

However, after an intense campaign by many interest groups to repeal the law,²⁵ Congress abolished MCCA's major provisions, including the prescription drug benefit, in December 1989.²⁶

In 1993, policymakers again considered a prescription drug benefit for seniors when President Bill Clinton included an outpatient prescription drug benefit as part of his proposed Health Security Act.²⁷ The plan allowed Medicare to use its negotiating power to obtain discounts on pharmaceuticals for seniors.²⁸ In 1994, the bill died after aggressive attacks from conservatives and interest groups who claimed that the plan required too much rationing and "government bureaucracy."²⁹

increased beneficiaries' premiums, and required seniors paying over \$150 in federal income taxes to pay "supplemental premiums." Medicare Catastrophic Coverage Act, *supra* note 21. These supplemental premiums were equal to 15% of the amount of federal income tax each beneficiary owed. *Id.* Congress capped seniors' supplemental premiums at \$800 per person and \$1600 per couple. *Id.*

²⁵ See Julie Rovner, *Senate Takes Up Prescription Drug Coverage for Seniors*, NPR, July 17, 2002, available at <http://npr.org/templates/story/story.php?storyId=1146806> (last visited Oct. 14, 2005). Many groups opposed the mandatory participation requirement and the supplemental premiums because beneficiaries had better prescription drug coverage through private plans or retiree benefits. *Id.*

²⁶ Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, 102 Stat. 683, *repealed by* Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. No. 101-234, 103 Stat. 1979 (codified as amended in scattered sections of 26 and 42 U.S.C.). Ultimately, the self-financing and mandatory participation requirements along with the law's failure to address nursing home care costs, which at the time were the leading cause of catastrophic medical expenses for seniors, spelled MCCA's demise. Oliver et al., *supra* note 3, at 299-300.

²⁷ Health Security Act, H.R. 1200, 103rd Cong. (1993). The plan proposed an \$11 per month increase to Medicare beneficiaries' premiums and required beneficiaries to meet a \$250 annual deductible before receiving any prescription drug benefits. *Id.* The plan required beneficiaries to pay 20% of the cost of each prescription up to an annual out-of-pocket maximum of \$1000. *Id.* The plan only covered generic drugs unless a beneficiary's physician certified that the beneficiary needed a brand name drug. *Id.*

²⁸ *Id.*

²⁹ Oliver et al., *supra* note 3, at 302 (citation omitted); Dana Priest, *Democrats Pull the Plug on Health Care Reform*, WASH. POST, Sept. 27, 1994, at A1.

In his 1999 State of the Union Address, President Bill Clinton proposed another Medicare outpatient prescription drug benefit.³⁰ Unlike his earlier plan, this proposal allowed the private sector to control drug management, negotiation, and competition.³¹ With the 2000 election looming, Congress simply ignored President Clinton's proposal.³²

By this time, increasing prescription drug costs caused Medicare HMO providers, "an important source of drug coverage for 15% of Medicare beneficiaries," to heavily restrict coverage by setting low prescription drug coverage ceilings or by eliminating prescription drug coverage.³³ Similarly, "Medigap and supplemental insurance providers that covered [seniors'] prescription drugs were raising premiums" to levels many beneficiaries could no longer afford.³⁴ Contemporaneously, prescription drug companies embarked on a media campaign, where they marketed prescription drugs directly to seniors as the key to a disease free future.³⁵

These factors illuminated the lack of a Medicare prescription drug benefit and increased demand for a benefit.³⁶ Further, in 2000, the Clinton administration announced projected federal budget surpluses ranging

³⁰ President Bill Clinton, State of the Union Address (Jan. 19, 1999). For a monthly premium of \$24 per beneficiary, the plan proposed to cover 50% of a beneficiary's drug spending, up to \$1,000 annually. David B. Kendall and Jeff Limoux, *The President's Medicare Reform Proposal*, (July 1, 1999), available at <http://www.ppionline.org/ppi-ci.cfm?contentid+8278knbjAreaID=1118subsecid=141> (last visited Oct. 14, 2005). The benefit would have been indexed annually, with monthly premiums rising to \$44 per beneficiary and coverage rising to \$2,500 annually. *Id.*

³¹ *Id.*; Oliver et al., *supra* note 3, at 307.

³² *See* Oliver et al., *supra* note 3, at 307.

³³ Jonathan Oberlander, *The Politics of Medicare Reform*, 60 WASH. & LEE L. REV. 1095, 1129 (2003) (citation omitted).

³⁴ *Id.*

³⁵ *Id.* at 1130.

³⁶ *See id.* ("The prospects of a genetic revolution on the horizon made it imperative to extend drug coverage to Medicare."); Thomas S. Rector and Patricia J. Venus, *Do Drug Benefits Help Medicare Beneficiaries Afford Prescribed Drugs?*, 23 HEALTH AFFAIRS 213 (2004), available at <http://www.healthaffairs.org>.

between \$131 billion in 2000 and \$381 billion in 2009.³⁷ These projected surpluses coupled with consumer demand for a Medicare prescription drug benefit drove elected officials and those seeking election to again consider the addition of an outpatient prescription drug benefit for Medicare recipients.³⁸

B. ENACTING A MEDICARE PRESCRIPTION DRUG BENEFIT.

In his fiscal year 2002 budget, newly elected President George W. Bush proposed a \$156 billion allocation for Medicare reform including a prescription drug assistance plan.³⁹ In July 2001, President Bush added to his proposal a discount prescription drug card program designed to allow seniors to purchase discounted prescription drugs through private Pharmacy Benefit Managers (“PBMs”).⁴⁰ The Bush administration designed the drug card to enhance card sponsors’ abilities to negotiate competitive rebates from drug manufacturers and pass the rebates to Medicare-eligible consumers.⁴¹ The administration estimated that the drug card would save seniors between 10% and 25% of retail prescription drug prices.⁴²

The administration assumed it could implement the discount drug card program without employing the Administrative Procedure Act’s⁴³

³⁷ *The Budget and Economic Outlook: Fiscal Years 2001-2010 Before the House Comm. on the Budget*, 105th Cong. 11 (2000) (statement of Dan L. Ripen, Director, Congressional Budget Office), available at <http://www.cbo.gov/ftpdocs/18xx/doc1839/021600dc.pdf> (last visited Oct. 7, 2005).

³⁸ Oberlander, *supra* note 33, at 1128-29. In fact, in the 2000 Presidential campaign, candidates Al Gore and George W. Bush supported the creation of a new Medicare Prescription Drug benefit. See Oliver et al., *supra* note 3, at 307.

³⁹ *A Blueprint for New Beginnings: A Responsible Budget for America’s Priorities*, Office of the President (2001), at 111-17, available at <http://www.whitehouse.gov/news/usbudget/blueprint/budtoc.html> (last visited Oct. 7, 2005).

⁴⁰ See Press Release, Remarks by the President on Medicare (July 21, 2001), available at <http://www.whitehouse.gov/news/releases/2001/07/20010712-1.html> (last visited Oct. 14, 2005).

⁴¹ See *id.*

⁴² *Id.*

⁴³ Administrative Procedure Act, 5 U.S.C. §§ 551-553 (2004). The APA mandates that “[g]eneral notice of proposed rule making shall be published in the

(“APA”) notice and comment process, an assumption that the National Association of Chain Drug Stores and the National Community Pharmacists’ Association challenged in court.⁴⁴ The court upheld the challenge and ruled that the Bush administration’s actions violated the APA.⁴⁵ The Bush administration then agreed to comply with the APA in formulating the Medicare Rx Discount Card program.⁴⁶

Thereafter, the Center for Medicare and Medicaid Services (“CMS”) published a proposed rule for its “Medicare-Endorsed Prescription Drug Card Assistance Initiative.”⁴⁷ Under the rule, CMS planned to: (1) designate certain prescription drug discount card programs as “Medicare-Endorsed”; and (2) determine which programs could participate in the Drug Card Assistance Initiative by evaluating each program’s “structure and experience, customer service, pharmacy network adequacy, [and] ability to offer manufacturer rebates or discounts.”⁴⁸ When the pharmaceutical industry challenged this proposed rule, the court ruled that the CMS lacked the statutory authority to implement this program.⁴⁹

Following this debacle, President Bush called upon Congress to enact immediately legislation to provide seniors with prescription drug benefits.⁵⁰ Deadlock took hold in Congress, as partisan debate raged over Medicare outpatient prescription drug plan costs, provisions, and the proposal to allow private PBMs to negotiate discounts on behalf of

Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law.” *Id.* § 553.

⁴⁴ See *Nat’l Ass’n of Chain Drug Stores v. Thompson*, No. 01-1554, 2001 U.S. Dist. LEXIS 14417, at *1 (D.D.C. Sept. 11, 2001).

⁴⁵ *Id.*

⁴⁶ See THOMAS C. FOX ET AL., HEALTH CARE FINANCIAL TRANSACTION MANUAL § 21.54 (2003).

⁴⁷ Medicare Program: Medicare-Endorsed Prescription Drug Card Assistance Initiative, 67 Fed. Reg. 10262 (Mar. 6, 2002).

⁴⁸ *Id.* at 10264.

⁴⁹ Oliver et al, *supra* note 3 at 307 (citing *Pear & Bumiller* 2003).

⁵⁰ *Id.*

Medicare recipients.⁵¹ The deadlock eased when Republicans gained control of the Senate in November 2002.⁵²

On March 4, 2003, President Bush released to the press his “Framework to Modernize and Improve Medicare,” which outlined only a general structure for a Medicare prescription drug benefit.⁵³ The proposed plan provided Medicare beneficiaries with three options: (1) to remain in traditional Medicare, obtain approximately 10% to 25% discounts on prescription drugs through the government-issued prescription drug discount card, and receive protection against catastrophic out-of-pocket drug expenses with no additional monthly premium; (2) to choose an enhanced Medicare, modeled after the Federal Employees Health Benefit Program, whereby beneficiaries could choose one of many private health plans providing prescription drug benefits, full coverage of preventative benefits, protection against high out-of-pocket drug costs, a single deductible, and additional benefits for low-income beneficiaries; or (3) to enroll in Medicare Advantage, whereby beneficiaries could choose a low-cost, high-coverage managed care plan including a subsidized drug benefit, with additional benefits for low-income seniors.⁵⁴ President Bush pledged \$400 billion in new spending over ten years to enact his proposal.⁵⁵

Partisan debate over the bill’s provisions stalled the President’s proposal until the Senate Finance Committee presented a bipartisan agreement in June 2003 that pushed Medicare prescription drug coverage forward.⁵⁶ The full Senate subsequently passed Medicare prescription drug coverage by a vote of seventy-six to twenty-one.⁵⁷ The House then undertook “an impassioned partisan debate over the proper roles of

⁵¹ Oliver et al., *supra* note 3, at 307-09. Many legislators wanted the federal government to negotiate Medicare prescription drug discounts instead. *Id.*

⁵² See *GOP Wins Senate, Holds House, CNN PROJECTS*, Nov. 6, 2002, <http://www.cnn.com/2002/ALLPOLITICS/11/06/02elec02.main.day/>

⁵³ See Press Release, *supra* note 41.

⁵⁴ H.R. 1, 108th Cong. (2003) (enacted).

⁵⁵ See Press Release, *supra* note 41. The \$400 billion in funding was split between a prescription drug benefit and other Medicare modernization measures beyond the scope of this article. *Id.*

⁵⁶ Oliver et al., *supra* note 3, at 310.

⁵⁷ Oliver et al., *supra* note 3, at 311.

government and private industry in delivering healthcare to the elderly.”⁵⁸ Finally, “despite partisan rancor and strong resistance from Democrats and some Republicans, the full House narrowly passed [the bill] by 216 to 215 votes . . . but only after an abnormally long roll call vote” where Vice President Dick Cheney and House leaders had to “persuade several GOP representatives to switch their votes at the last moment to save the measure.”⁵⁹

A conference committee convened to hammer out the final bill, as the House and Senate versions were markedly different.⁶⁰ On November 15, 2003, the conference committee agreed on a new version of the bill.⁶¹ Subsequently, both houses undertook a vote on the new bill.⁶² In the House of Representatives, by 3:00 A.M. on Saturday, November 22, the bill appeared to be dead when “at the end of the normal 15 minutes allowed for voting, the bill was losing by 15 votes.”⁶³ However,

⁵⁸ *Id.* at 312.

⁵⁹ *Id.*

⁶⁰ *Id.* at 312. Only two Democrat senators, both of whom supported market, as opposed to government, regulation were allowed to participate in the bill’s daily discussions. *Id.* “This ‘hardball’ approach did not ensure a smooth process, however, as it still took four months of negotiations to craft a package that . . . attract[ed] enough votes to get the bill to the president’s desk.” *Id.* at 313.

⁶¹ Bill Summary and Status for the 108th Congress, H.R. 1 (2003), *supra* note 58.

The 678-page conference report included many of the features that had come to be widely accepted in earlier proposals, such as the [drug] discount card, additional assistance for low-income beneficiaries, a substantial gap in benefits for individuals with high drug costs (“the doughnut hole”), and the use of private pharmacy benefit managers in lieu of direct governmental regulation. Yet the bill reflected “concession” more than “compromise,” with the final provisions on some of the most controversial issues watered down so as to become almost meaningless to their proponents.

Oliver et al., *supra* note 3, at 316.

⁶² Bill Summary and Status for the 108th Congress, H.R. 1 (2003), *supra* note 58.

⁶³ Oliver et al., *supra* note 3, at 321.

[b]etween the normally apolitical hours of 3 and 6 on a Saturday morning, the House voted, by the tiniest of margins, to pass a hugely controversial Medicare bill. During the vote, which was of unprecedented length, the House Republican leadership cajoled, berated and twisted arms, barely controlling a conservative revolt, while President Bush, jet-lagged from his trip to Europe, called up recalcitrant members one by one.⁶⁴

Finally, the legislation passed by a vote of 220-215 in the House of Representatives, after the Democrats thought they had the votes to defeat it.⁶⁵

On November 25, 2003, the Senate called the bill up for a final vote.⁶⁶ For some time, it seemed that the bill's opponents would block the legislation on a budgetary point of order, based on claims that the bill's provisions exceeded the \$400 billion financial cap the President established for the bill.⁶⁷ "After colleagues beseeched him to support the President and his party, former Senate Majority Leader Trent Lott (R-Miss.) gave in and cast the deciding vote to waive the budget rules and proceed to an up-or-down vote on the Medicare bill itself."⁶⁸ The legislation subsequently passed the full Senate by a vote of fifty-four to forty-four.⁶⁹ On December 8, 2003, President Bush signed into law the

⁶⁴ *Id.* at 321-22.

⁶⁵ Oberlander, *supra* note 33, at 1136.

⁶⁶ Bill Summary and Status for the 108th Congress, H.R. 1 (2003), *supra* note 58.

⁶⁷ Oliver et al., *supra* note 3, at 321.

⁶⁸ *Id.*

⁶⁹ Bill Summary and Status for the 108th Congress, H.R. 1 (2003), *supra* note 58. A January 2004 report from the President's Office of Management and Budget projected the new law would cost the federal government \$534 billion over ten years, a full \$139 billion more than the figure legislators relied on when passing the bill. Oliver, *supra* note 3, at 323. A subsequent investigation revealed that Thomas Scully, the former head of the CMS, threatened to fire the chief Medicare actuary, Richard S. Foster if Foster disclosed to Congress the actual cost of the plan. Robert Pear, *Inquiry Proposes Penalties For Hiding Medicare Data*, N.Y. TIMES, Sept. 8, 2004. Legislators from both parties indicated that they would not have passed the bill in its current form if CMS had published the actual cost estimate. *Id.*

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, designed, in part, to provide Medicare beneficiaries with outpatient prescription drug coverage for the first time in Medicare's history.⁷⁰

C. THE PROVISIONS OF THE MEDICARE PRESCRIPTION DRUG ACT.

1. The Discount Prescription Drug Card Program.

As part of the MMA, Congress and President Bush designed the Medicare Prescription Drug Discount Card program to provide beneficiaries with temporary prescription drug cost assistance before Medicare-sponsored prescription drug coverage begins on January 1, 2006.⁷¹ Program enrollment began in May 2004, and enrolled Medicare beneficiaries first obtained program benefits in June 2004.⁷² All Medicare beneficiaries were eligible to enroll in the voluntary program except those receiving Medicaid prescription drug assistance, military health insurance, employer group health insurance, or federal health insurance benefits.⁷³ The drug discount card program terminates on December 31, 2005 when Medicare's outpatient prescription drug coverage begins.⁷⁴

The drug discount card program requires Medicare to contract with private companies to offer prescription drug discount cards to Medicare beneficiaries.⁷⁵ Private companies approve beneficiaries' applications and

⁷⁰ Bill Summary and Status for the 108th Congress, H.R. 1 (2003), *supra* note 58; Gerard F. Anderson et al., *Doughnut Holes and Price Controls*, HEALTH AFFAIRS Web Exclusive (July 21, 2004), at <http://www.healthaffairs.org>.

⁷¹ Juliette Cubanski et al., *Savings From Drug Discount Cards: Relief For Medicare Beneficiaries?* (Apr. 14, 2001), HEALTH AFFAIRS W4-198, W4-198, <http://www.healthaffairs.org>.

⁷² Centers for Medicare and Medicaid Services, *Medicare Prescription Drug Discount Card and Transitional Assistance Program*, at <http://www.cms.hhs.gov/discountdrugs/overview.asp>; Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card* 7, <http://www.medicare.gov>.

⁷³ Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card*, *supra* note 73, at 5.

⁷⁴ Cubanski et al., *supra* note 72, at W4-199.

⁷⁵ Center for Medicare and Medicaid Services, *Introducing Medicare-Approved Drug Discount Cards*, <http://www.medicare.gov>. Currently, there are more than seventy Medicare-approved discount drug cards available throughout the country, but some cards serve limited geographical areas. Marc Steinberg,

then distribute the prescription drug discount cards.⁷⁶ Each private provider can charge a beneficiary up to \$30 annually for the card.⁷⁷

Prescription drug savings vary, depending on which discount card the beneficiary selects.⁷⁸ Companies offering cards decide upon and publish a list of discounted drugs and may change their discounted drug list and prices at any time.⁷⁹ The providers must make available to the beneficiaries a list of the specific pharmacies where beneficiaries can obtain their discounted prescription medications.⁸⁰

Once a beneficiary chooses a drug discount card, the beneficiary generally may not switch to another card for the remainder of the calendar year.⁸¹ Medicare beneficiaries can obtain assistance in selecting a plan by entering their medications on a Medicare-sponsored Internet form or by calling a Medicare customer service representative for assistance.⁸² These services recommend to the beneficiary the most financially favorable plan in the beneficiary's geographic area, taking into consideration the drugs the beneficiary uses.⁸³

The MMA discount drug card program does not mandate that discount drug card providers meet any minimum prescription drug discount threshold, but the CMS claims that using a discount drug card

Gearing Up: States Face the New Medicare Law 4, (Sept. 2004), <http://www.familiesusa.org>.

⁷⁶ Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card*, *supra* note 73, at 10.

⁷⁷ Center for Medicare and Medicaid Services, *Introducing Medicare-Approved Drug Discount Cards*, *supra* note 76.

⁷⁸ Stacey Range and Chris Andrews, *Seniors Critical of Medicare's Prescription Drug Card Program*, LANSING ST. J., Sept. 20, 2004, at 1A.

⁷⁹ Steninberg, *supra* note 76, at 4.

⁸⁰ Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card*, *supra* note 73, at 12.

⁸¹ *Id.* at 9. A beneficiary may only change programs if he or she: (1) moves to a state that does not offer his or her discount card; (2) joins or leaves a Medicare Managed Care plan; (3) enters or leaves a long-term care facility; or (4) is no longer offered the card by the card's provider. *Id.* If the beneficiary must change plans for one of the above-listed reasons, the beneficiary must pay the \$30 fee to his or her new plan each time the beneficiary switches plans. *Id.* at 11.

⁸² Range and Andrews, *supra* note 79.

⁸³ *Id.*

could save a beneficiary between 10% and 15% on total drug spending and up to 25% on certain individual drugs.⁸⁴ The discount cards may provide lower cost prescription drugs to Medicare beneficiaries by negotiating discounts with drug makers and pharmacies, reducing pharmacy-dispensing fees, and requiring beneficiaries to use the Internet and/or mail order for drug purchasing.⁸⁵

In addition to the discounts all beneficiaries obtain with the drug cards, “low income” Medicare beneficiaries qualify for additional drug discount card assistance.⁸⁶ Notably, low-income beneficiaries are not required to pay the program’s \$30 enrollment fee.⁸⁷ Additionally, low-income seniors may be entitled to a \$600 credit on the Medicare-approved discount drug card of their choice.⁸⁸ Beneficiaries apply for the \$600 credit through their discount prescription drug card provider,⁸⁹ and the CMS applies the credit to each beneficiary’s discount prescription drug card once CMS confirms a beneficiary’s income eligibility.⁹⁰

⁸⁴ Cubanski et al., *supra* note 72, at W4-199.

⁸⁵ *Id.* at W4-198.

⁸⁶ Center for Medicare and Medicaid Services, *Introducing Medicare-Approved Drug Discount Cards*, *supra* note 76. To qualify for Medicare “low income” benefits, beneficiaries must have an income of less than 135% of poverty, which is \$12,569 for a single person or \$16,862 for a married couple for the 2005 tax year. *Id.*; *The Medicare Prescription Drug Benefit Fact Sheet 2* (Sep. 2005), <http://www.kff.org/medicare/upload/7044-02.pdf>. A beneficiary’s income includes money received through Social Security retirement benefits, Railroad retirement, the federal government, disability benefits, Veteran benefits, and any other benefits a beneficiary reports for federal income tax purposes. Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card*, *supra* note 73, at 4.

⁸⁷ Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card*, *supra* note 73, at 18.

⁸⁸ Center for Medicare and Medicaid Services, *Introducing Medicare-Approved Drug Discount Cards*, *supra* note 76. In addition to meeting income requirements, to qualify for the \$600 subsidy, a beneficiary cannot have other health insurance that provides outpatient prescription drug coverage. Center for Medicare and Medicaid Services, *Guide to Choosing a Medicare-Approved Drug Discount Card*, *supra* note 73, at 5. Moreover, if a beneficiary applies for the credit after March 31, 2005, the \$600 credit is prorated based upon the days remaining in the calendar year. *Id.* at 19.

⁸⁹ *Id.* at 18.

⁹⁰ *Id.*

Beneficiaries may use the credit immediately to purchase all prescription drugs.⁹¹

While using the \$600 credit, a low-income beneficiary is only required to pay a 5% to 10% coinsurance on the discounted cost of a prescription.⁹² The pharmacy where a beneficiary purchases his or her discounted drugs charges the beneficiary the required coinsurance and deducts from the drug discount card the amount a beneficiary spends on prescriptions.⁹³ The beneficiary's pharmacy also provides a statement to the beneficiary indicating the amount remaining on the beneficiary's drug card.⁹⁴ Once the beneficiary exhausts the \$600 subsidy, he or she must pay the discount drug card provider's full discounted price for prescription drugs.⁹⁵

2. *The 2006 Outpatient Prescription Drug Benefit Plan.*

The MMA outpatient prescription drug benefit contains provisions that promote private insurance and managed care.⁹⁶ Under the benefit, which takes effect January 1, 2006, beneficiaries may enroll in an integrated Medicare Advantage Plan ("MAP") to receive all of Medicare's covered benefits, including prescription drugs, or they may remain in the traditional Medicare fee-for-service program and separately enroll in a private prescription drug plan ("PDP").⁹⁷ In both programs, private insurers will deliver the prescription drug benefit.⁹⁸

Through its cost sharing structure, MMA requires the beneficiary to pay the first \$250 of outpatient prescription drug expenses before

⁹¹ *Id.* at 17. A beneficiary can even use the \$600 subsidy to purchase prescription drugs not included on the provider's discount drug list. *Id.*

⁹² *Id.* at 20. Whether a beneficiary pays 5% or 10% coinsurance depends on the beneficiary's annual income when he or she applied for the Medicare-approved discount drug card and the \$600 credit. *Id.*

⁹³ *Id.* at 21.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ Oberlander, *supra* note 33, add. at 1134.

⁹⁷ *The Medicare Prescription Drug Law Fact Sheet*, *supra* note 87, at 1.

⁹⁸ Oberlander, *supra* note 33, add. at 1134.

becoming eligible for the Medicare outpatient prescription drug benefits.⁹⁹ In addition to this \$250 deductible, most Medicare beneficiaries will pay a \$35 monthly premium for prescription drug coverage.¹⁰⁰ The deductible and monthly premiums will cover 75% of a beneficiary's annual prescription drug expenses up to \$2,250.¹⁰¹ Beneficiaries then pay all prescription drug costs between \$2,250 and \$5,100.¹⁰² Catastrophic coverage begins above the \$5,100 threshold, with Medicare paying 95% of a beneficiary's annual prescription drug costs.¹⁰³

Similar to the Medicare Prescription Drug Discount Card program, the Medicare outpatient prescription drug plan devotes substantial resources to providing low-income beneficiaries with prescription drug cost-sharing assistance.¹⁰⁴ The plan covers 100% of prescription drug

⁹⁹ Anderson et al., *supra* note 71, at W4-402 n.2. A beneficiary can only fulfill the plan's required financial contribution by using prescription drugs that are in the regional private provider's established drug formulary. Geraldine Dallek, *Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* 8 (July 2004), <http://www.kff.org/medicare/upload/Consumer-Protection-Issue-Raised-by-the-Medicare-Prescription-Drug-Improvement-and-Modernization-Act-of-2003.pdf>.

¹⁰⁰ Anderson et al., *supra* note 71, at W4-397. The deductible and premium levels for the drug benefit will be indexed annually in proportion to the increase in the benefit's cost. Marilyn Moon, *supra* note 3, at 6. Therefore, the \$3600 in out-of-pocket costs that a beneficiary over 150% of the poverty level must pay in 2006 is expected to rise 78% to \$6400 in 2013. *Id.* At the same time, Medicare beneficiaries' monetary benefits and low-income protections are expected to rise at about half that rate. *Id.* at 7

¹⁰¹ Anderson et al., *supra* note 71, at W4-397.

¹⁰² *Id.* This portion of drug costs that beneficiaries must pay is commonly referred to as the "donut hole." Marilyn Moon, *supra* note 3, at 3. This donut hole provision restricts a beneficiary's health insurance plan from filling the benefit's gap. *Id.* at 4. Only individuals, family members, and state pharmaceutical assistance programs can provide assistance that counts toward the out-of-pocket spending requirement. *Id.*

¹⁰³ Anderson, et al., *supra* note 71, at W4-397. Before catastrophic coverage begins at the \$5100 threshold, each beneficiary must pay \$3,600 in out-of-pocket prescription drug costs. Moon *supra* note 3, at 4. Seniors' prescription drug spending will be tracked on their Medicare prescription drug cards. Telephone Interview with Dana Gray, Legislative Aide to Congresswoman Ellen Tauscher (Jan. 20, 2004).

¹⁰⁴ Mays et al., *supra* note 4, at i.

costs and premiums above the \$5100 catastrophic threshold for those seniors who are dually eligible for Medicare and Medicaid.¹⁰⁵ Below the out-of-pocket threshold, dually eligible beneficiaries with incomes below 100% of the poverty line will have co-payments of \$1 for generic drugs and \$3 for name brand drugs, with no monthly premium or annual deductible.¹⁰⁶ Dual eligible beneficiaries with incomes above the poverty line will have co-payments of \$2 for generic drugs and \$5 for brand name drugs, with no deductible or monthly premium.¹⁰⁷

Non-dual-eligible low-income beneficiaries with income between 100% and 135% of the poverty line and limited assets¹⁰⁸ pay no monthly premiums or deductible and pay \$2 co-payments for generic drugs and \$5 for name brand prescription drugs.¹⁰⁹ These beneficiaries have no cost-sharing or deductible responsibilities above the \$5,100 catastrophic threshold.¹¹⁰ For beneficiaries with income between 135% and 150% of

¹⁰⁵ *Id.* at i-ii. Medicaid will no longer offer drug coverage to dual eligibles. *The Medicare Prescription Drug Law Fact Sheet*, *supra* note 87, at 2. Instead, MMA requires dual eligibles to enroll in either a PDP or MAP prescription drug plan. *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, 108th Cong. (2004) (statement of Dr. Mark B. McClellan, Administrator, Centers for Medicare and Medicaid Services). Any dual eligible beneficiary who fails to enroll in either a PDP or an MAP will be automatically, randomly enrolled into a PDP that has a monthly beneficiary premium equal to or less than the low-income beneficiary's subsidy. *Id.*

¹⁰⁶ White Paper, *The New Medicare Prescription Drug Benefit: Prescription Drug Assistance and Security for All Beneficiaries* 1 (Nov. 22, 2004), at <http://www.whitehouse.gov>.

¹⁰⁷ Dallek, *supra* note 100, at 25.

¹⁰⁸ *Id.* For a beneficiary below 135% of the poverty line to qualify for the low-income plan benefits, the beneficiary cannot have more than \$6000 in assets if single or \$9000 if married. *Id.* Assets do not include a family home, household goods, personal effects such as wedding rings, a vehicle, or a burial plot. *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, *supra* note 106. The asset test counts only liquid assets such as stocks, bonds, savings accounts and real estate holdings other than the beneficiary's primary residence. *Id.*

¹⁰⁹ Dallek, *supra* note 100, at 25.

¹¹⁰ *The Medicare Prescription Drug Law Fact Sheet*, *supra* note 87.

the poverty level and limited assets,¹¹¹ the plan provides premium subsidies based on a sliding income scale.¹¹² Additionally, these beneficiaries must pay a \$50 annual deductible, 15% coinsurance up to MMA's out-of-pocket threshold, and \$2 to \$5 co-payments above the threshold.¹¹³ Once a beneficiary's income exceeds 150% of the poverty line, the beneficiary is subject to the same deductibles, co-payments, donut hole provision and catastrophic benefits as all other plan beneficiaries.¹¹⁴

The MMA mandates that private, regional insurers offer prescription drugs, unless a private insurer declines to enter a geographical area.¹¹⁵ If two or more risk-bearing plans, including at least one PDP, are not located in the same regional area,¹¹⁶ the MMA mandates a federally run drug plan, where the government absorbs the insurance risk and contracts with a PBM or other provider to process claims and administer the plan.¹¹⁷ The fallback plan will remain only until a new private plan enters the market.¹¹⁸

The MMA requires regional private plans to accept all eligible enrollees in their service area, regardless of a beneficiary's age or health status.¹¹⁹ Additionally, plans must provide uniform benefits and premiums for all enrollees in the region.¹²⁰ The law specifically forbids a private provider from discriminating against enrollees based on the beneficiary's health status.¹²¹

¹¹¹ Dallek, *supra* note 100, at 25. In this category, assets are limited to \$10,000 per individual or \$20,000 per couple. *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ Moon, *supra* note 3, at 5.

¹¹⁵ *Id.* at 7. The MMA prohibits the government from negotiating drug prices. *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance, supra* note 106.

¹¹⁶ *The Medicare Prescription Drug Law Fact Sheet, supra* note 87.

¹¹⁷ Moon, *supra* note 3, at 7. This federally run plan is called a "fallback plan." *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance, supra* note 106.

¹²⁰ *Id.*

¹²¹ *Id.*

The MMA permits private providers to utilize drug formularies, where the private provider can limit the number of drugs covered in a specific therapeutic category or class to two.¹²² The MMA encourages this formulary structure in order to allow private providers to purchase large volumes of prescription drugs at lower overall costs.¹²³ In addition to formulary restrictions, plans are free to set co-payments for specific drugs and force the use of generic instead of brand name medications, so long as the private providers follow the benefit's general structure.¹²⁴

The MMA requires each participating plan to develop an appeals process, whereby a beneficiary can challenge a plan's denial of a prescription drug due to formulary restrictions.¹²⁵ Each plan designs and implements its own specific appeals process, and only the enrollee or the enrollee's authorized representative can file an appeal.¹²⁶ As part of the

¹²² Moon, *supra* note 3, at 8. A plan's formulary is its list of covered prescription medications. *Id.* In April 2004, the federal government awarded United States Pharmacopeia (USP) a \$1.1 million contract to develop guidelines regarding which medications private providers should cover under the plan. *Rx Drugs: Senators Urge Revision of Proposed Medicare Formulary*, AMERICAN HEALTHLINE, (Oct. 8, 2004). USP developed the guidelines with the help of beneficiaries, care providers, drug companies and companies selling prescription drug insurance. *Id.* In August 2004, USP issued draft guidelines including 146 categories and classes. *Some Drugs Could be Left Out Under Proposed USP Guidelines*, WASH. DRUG LETTER, Aug. 30, 2004. In December 2004, USP issued its final recommendations to Medicare officials, which contained the same number of prescription drug categories and classes. David Glendinning, *Medicare Drug Choices Called Too Restrictive*, AMERICAN MEDICAL NEWS, Jan. 24, 2005, <http://www.ama-assn.org/amednews/2005/01/24/gv110124.htm>. Medicare prescription drug plans are not required to comply with the guidelines, but "doing so helps to assure that they do not run afoul of the law's prohibition of drug formularies that discriminate against Medicare enrollees with costly conditions." *Rx Drugs: Senators Urge Revision of Proposed Medicare Formulary*, *supra*.

¹²³ Robert Pear, *Medicare Rules Set off a Battle on Drug Choices*, N.Y. TIMES, Sept. 26, 2004.

¹²⁴ Moon, *supra* note 3, at 8.

¹²⁵ *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, *supra* note 106.

¹²⁶ *Id.* Each appeals process must allow the following steps: (1) the drug plan's redetermination; (2) an outside organization's reconsideration; (3) an administrative law judge's consideration; (4) a Medicare Appeals Council review; and (5) a beneficiary filing suit in a federal district court. Robert Pear,

appeal, the beneficiary's prescribing physician must certify that the formulary drugs are not effective and/or have adverse side effects for the beneficiary.¹²⁷ If the appeal is granted, the beneficiary's plan will cover the non-formulary drug.¹²⁸

Enrollment in the outpatient prescription drug plan is voluntary.¹²⁹ Initial enrollment for the new benefit begins November 15, 2005 and ends May 15, 2006.¹³⁰ After the initial enrollment period, open enrollment in the plan will occur every year between November 15 and December 31 for the following benefit year.¹³¹

Beneficiaries without prior "credible drug coverage" must sign up for Medicare drug coverage during their initial enrollment period.¹³² Absent proof of previous actuarially equivalent prescription drug insurance coverage, beneficiaries who delay enrolling past the Medicare designated prescription drug plan enrollment period will be assessed substantial financial penalties, with late enrollees' premiums rising by at least 1% for each month a beneficiary delays enrollment.¹³³ The penalty provision contains only one exception for those beneficiaries whose insurers failed to inform them that the beneficiary's insurance coverage

New Medicare Drug Rules Balance Access And Costs, N.Y. TIMES, Jan. 22, 2005, at A11.

¹²⁷ *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, *supra* note 106.

¹²⁸ *Id.*

¹²⁹ White Paper, *The New Medicare Prescription Drug Benefit*, *supra* note 107, at 1.

¹³⁰ *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, *supra* note 106.

¹³¹ *Id.*

¹³² *Id.* Credible drug coverage must be comparable to that offered under the Medicare outpatient prescription drug program. *Id.*

¹³³ Moon, *supra* note 3, at 8. For example, if a senior does not join a Medicare outpatient prescription drug plan during his or her initial enrollment period but decides to enroll thirty-six months later, the beneficiary must then pay a monthly premium 36% higher than the beneficiary's counterparts who enrolled during the initial enrollment period. Dallek, *supra* note 100, at 15. Premium increases can be higher if the Secretary certifies actuarial costs are higher. Moon, *supra* note 3, at 8.

was not equivalent to the benefits offered under the Medicare outpatient prescription drug plan.¹³⁴

Once a beneficiary enrolls in the program, the MMA restricts beneficiaries' freedom to change plans.¹³⁵ During the transition period, beneficiaries enrolling in the outpatient prescription drug plan will be able to change plans between January and June of 2006.¹³⁶ Beginning January 2007, lock-in provisions become more restrictive and dictate that

[b]eneficiaries can change plans at the end of 2006 (from November 15 to December 31) for enrollment on January 1 of the following year and once during the first three months of the year. However, choice during these three months is limited: if [a beneficiary] want[s] to retain drug coverage, PDP enrollees can only switch to a[n] MA[P] organization (but not another PDP) and MA[P] enrollees only to another MA[P] organization or to original Medicare and a PDP.¹³⁷

III. ANALYSIS

A. THE LAW DOES NOT PROVIDE MEDICARE BENEFICIARIES WITH UNDERSTANDABLE, MEANINGFUL PRESCRIPTION DRUG BENEFITS.

The MMA is not the comprehensive prescription drug benefit that policymakers promised. First, disappointing program enrollment figures from the Medicare discount prescription drug card program suggest that seniors are neither partaking in the plan nor enjoying the reduction in

¹³⁴ *Id.* at 16. The plan does not allow a late enrollment penalty waiver for those beneficiaries who fail to enroll due to their lack of understanding of the Medicare outpatient prescription drug program. *Id.*

¹³⁵ *Id.* at 17.

¹³⁶ *Id.*

¹³⁷ *Id.* However, beneficiaries can join or change plans during the year if: (1) they lose "credible prescription drug coverage"; (2) they move out of their plan's service area or their plan stops offering service; (3) they join an MAP when they are first eligible for Medicare and quit within one year; or (4) their enrollment in a plan was an "error in enrollment." *Id.*

prescription drug costs that policymakers promised.¹³⁸ The disappointing enrollment numbers suggest that the discount drug card program is not a comprehensible program that delivers large scale, meaningful drug cost relief to either regular or low-income Medicare beneficiaries. Furthermore, the MMA outpatient prescription drug benefit has its own shortcomings, including insufficient efforts to educate beneficiaries about the benefit, largely inadequate plan and drug choices, and a failure to establish a comprehensive prescription drug benefit for Medicare eligible seniors.

1. The Medicare Prescription Drug Discount Card Program's Failure to Provide Tangible Benefits.

Policymakers touted the discount drug card program as one that would provide seniors with moderate drug cost relief until the Medicare outpatient prescription drug benefit commences in 2006.¹³⁹ Policymakers also designed the program to provide low-income seniors with substantial financial assistance for purchasing prescription medications.¹⁴⁰ Unfortunately, the program is not an effective solution.¹⁴¹

i. Low Enrollment in the Discount Drug Card Program.

Since the program's inception, officials have struggled to enroll Medicare-eligible seniors.¹⁴² In fact, current estimates indicate that less than six million beneficiaries have signed up for the discount drug card program out of the 42 million eligible.¹⁴³ Enrollment rates for low-income

¹³⁸ *FTCR: Bush and Kerry Invited to Join Florida Seniors on Board the Rx Express to Buy Lower Cost Prescriptions in Canada*, U.S. NEWSWIRE, Sept. 22, 2004.

¹³⁹ *Medicare Prescription Drug Discount Card and Transitional Assistance Program*, *supra* note 73.

¹⁴⁰ See discussion, *supra* Part II.C.1.

¹⁴¹ Dallek, *supra* note 100, at 9.

¹⁴² Dean Olsen, *Seniors Urged to Use Drug Cards*, THE ST. J.-REG., Dec. 7, 2004, at 9.

¹⁴³ *Id.* The CMS had hoped to enroll 7.4 million of the 42 million eligible Medicare beneficiaries in the drug discount card program by the end of 2005. *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, *supra* note 106.

beneficiaries are also disappointing. Currently, over 1 million low-income Medicare beneficiaries receive the \$600 annual credit,¹⁴⁴ yet an estimated 5.8 million Medicare beneficiaries are eligible.¹⁴⁵ This low enrollment is attributable to several causes, including poor beneficiary education,¹⁴⁶ program complexity,¹⁴⁷ and an overabundance of discount drug card choices.¹⁴⁸

Seniors have complained that the discount drug card program is too complex.¹⁴⁹ Many beneficiaries cited confusion with the drug card plan as a reason they decided not to enroll.¹⁵⁰ Indeed, Medicare beneficiaries have found it hard to choose amongst “dozens of cards offering different discounts on different drugs.”¹⁵¹ Additionally, beneficiaries have avoided the program’s complicated enrollment paperwork required to acquire a Medicare-approved card¹⁵² and have complained that they are skeptical of the program.¹⁵³ Lastly, many seniors have waited months to receive discount drug cards or have never received benefits at all.¹⁵⁴

¹⁴⁴ Range and Andrews, *supra* note 79; *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance*, *supra* note 106.

¹⁴⁵ The Medicare Prescription Drug Law Fact Sheet, *supra* note 87.

¹⁴⁶ *FTCR: Bush and Kerry Invited to Join Florida Seniors on Board the Rx Express to Buy Lower Cost Prescriptions in Canada*, *supra* note 139.

¹⁴⁷ *Id.*; Range and Andrews, *supra* note 79.

¹⁴⁸ *FTCR: Bush and Kerry Invited to Join Florida Seniors on Board the Rx Express to Buy Lower Cost Prescriptions in Canada*, *supra* note 139.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Medicare: NYT Examines Confusion, Politics Over New Law*, AMERICAN HEALTH LINE, Oct. 12, 2004. In fact, a recent Merck phone survey found that almost 90% of Medicare beneficiaries had not signed up for a Medicare prescription drug discount card. Olsen, *supra* note 143. Almost 60% of those seniors indicated that there were too many drug discount cards to figure out which one was their best option. *Id.*

¹⁵² *Medicare: Drug Card Enrollment Falls Short*, HEALTH INS. LAW WKLY., Jan. 2, 2005.

¹⁵³ Range and Andrews, *supra* note 79.

¹⁵⁴ *Id.*

ii. *Marginal Payoffs from the Discount Drug Card Program.*

Surveys also show that seniors find the drug card program's discounts are not as lucrative as promised.¹⁵⁵ In fact, an individual's "savings from Medicare-approved discount cards . . . depend[s] on many factors, including the number, type, and duration of medications taken; initial out-of-pocket drug costs; where prescriptions are filled; discounts offered on drugs consumed; and retail or mail-order prices that would otherwise have been paid."¹⁵⁶ Moreover, many pharmacies already offer seniors discounts similar to those offered by a Medicare-approved discount prescription drug card,¹⁵⁷ thereby allowing seniors to obtain the same prescription drug discounts without signing up for or paying the costs associated with a discount drug card.¹⁵⁸

iii. *Important Policy Lessons for the 2006 Outpatient Prescription Drug Benefit.*

These disappointing enrollment figures combined with the program's complexity and inadequate drug discounts illustrate that the

¹⁵⁵ See *FTCR: Bush and Kerry Invited to Join Florida Seniors on Board the Rx Express to Buy Lower Cost Prescriptions in Canada*, *supra* note 139; Olsen, *supra* note 143. A 2004 study found that Medicare beneficiaries' cost savings while using the discount drug cards averaged 17.4% over current retail prices. Cubanski et al., *supra* note 72, at W4-208.

¹⁵⁶ *Id.* at W4-206. This study found that drug card discounts vary widely. *Id.* at W4-198. The same study predicted that those seniors who lack prescription drug coverage and incur large out-of-pocket costs would see some relief but would still incur sizable out-of-pocket costs. *Id.* at W4-208. However, the study also suggested that low-income Medicare beneficiaries who enrolled would almost certainly benefit from the drug card, in large part due to the program's \$600 beneficiary drug subsidy. *Id.*

¹⁵⁷ Milt Freudenheim, *Drugstores Fret as Insurers Demand Pills by Mail*, N.Y. TIMES, Jan. 1, 2005. For example, CVS pharmacy offers customers the option to purchase a ninety-day supply of prescription drugs at CVS pharmacies for the same price as mail ordering the prescriptions. *Id.*; see also Cubanski et al., *supra* note 72, at W4-207 (indicating that pharmacies offering senior discounts reduce savings generated by the Medicare-approved drug discount card).

¹⁵⁸ Freudenheim, *supra* note 158.

discount drug card program has not benefited seniors to the degree policymakers projected. Seniors consistently fail to enroll in the program, indicating that the vast majority of seniors do not realize the prescription drug discounts that policymakers promised. Additionally, the program's voluntary enrollment provision and inclusion of an excessive number of card options make the program a complex maze that many seniors refuse to navigate. The program's shortcomings are certainly disappointing to many, including those Medicare beneficiaries who desperately need prescription drug cost assistance and those who believed that the discount drug program would provide substantial assistance with Medicare beneficiaries' prescription drug costs.

The program's results, although disappointing, offer valuable lessons to policymakers and the President as the implementation of the MMA's outpatient prescription drug benefit nears. First, because the outpatient prescription drug benefit will also include a confusing cost-sharing system and substantial enrollment paperwork,¹⁵⁹ policymakers must adequately fund beneficiary education programs explaining the program's benefits and enrollment processes. Well-funded educational efforts will help to ensure that disappointing enrollment figures do not undermine the outpatient prescription drug program.

Policymakers should also require all Medicare-eligible beneficiaries to enroll in the program. A mandatory program will attract both healthy and sick beneficiaries, which will keep the program's costs at a reasonable level. Additionally, a mandatory program will maintain all Medicare beneficiaries' interest in the program, which will help to ensure that the program continues to receive adequate funding.

Finally, policymakers should enact a provision to permit government-administered negotiation of beneficiaries' prescription drug prices. Through bulk discounts, a government-administered program will provide lower prescription drug costs to all Medicare beneficiaries, including those who do not qualify for low-income assistance or incur extremely high out-of-pocket prescription drug costs.

2. The Shortcomings of the 2006 Outpatient Prescription Drug Benefit.

The MMA outpatient prescription drug benefit falls short of being a comprehensive drug benefit on many levels. First, the beneficiary

¹⁵⁹ See discussion, *supra* Part II.C.2.

educational component is “woefully underfunded,”¹⁶⁰ suggesting that without additional funding and outreach, many beneficiaries will forgo program enrollment simply due to a lack of knowledge and understanding of the program.¹⁶¹ Additionally, the program’s inadequate plan and drug choices indicate that the outpatient prescription drug program will not reduce many seniors’ prescription drug costs as promised or give them meaningful choices between different drugs and plans.¹⁶² This may also lead many seniors to forgo program enrollment.¹⁶³ Finally, the program’s relatively stingy drug benefits for those beneficiaries without low-income assistance or high out-of-pocket drug costs underscore the program’s failure to establish a comprehensive prescription drug benefit for all Medicare eligible seniors.¹⁶⁴

i. Insufficient Efforts to Educate Beneficiaries about the Outpatient Prescription Drug Program’s Benefits.

With the MMA outpatient prescription drug program’s inception looming, policymakers have provided only limited outpatient program information to Medicare beneficiaries.¹⁶⁵ In fact, although the program begins January 1, 2006,¹⁶⁶ a recent survey indicates that 60% of seniors did not even know that the President and Congress had implemented a Medicare prescription drug benefit.¹⁶⁷ In fact, at the time of this paper’s submission, CMS still had not specifically defined or implemented many

¹⁶⁰ Dallek, *supra* note 100, at 12.

¹⁶¹ *Id.*

¹⁶² *Id.* at 3-4.

¹⁶³ *Id.*

¹⁶⁴ Mays et al., *supra* note 4, at vii.

¹⁶⁵ Anderson et al., *supra* note 71. Tricia Neuman, the Kaiser Family Foundation’s Director of the Medicare Policy Project, indicated that “[s]eniors are very much unaware of what [is] coming their way.” *Medicare: NYT Examines Confusion, Politics Over New Law*, *supra* note 152. CMS has designed a multifaceted approach to educate Medicare beneficiaries, including print materials, toll-free telephone services, the Internet, and several regional counseling and education providers. Moon, *supra* note 3, at 12. However, these efforts are not properly funded. *Id.*

¹⁶⁶ Cubanski et al., *supra* note 72, at W4-199.

¹⁶⁷ Anderson et al., *supra* note 71, at W4-396.

of the program's provisions,¹⁶⁸ making current education efforts incomplete at best.

Currently, the law earmarks just \$1 billion to cover all aspects of the MMA's implementation, including beneficiary education.¹⁶⁹ The fraction of this amount designated for beneficiary education must suffice to educate all beneficiaries¹⁷⁰ regarding the program's enrollment requirements and penalties, plan choices, cost sharing requirements, and benefits for low-income beneficiaries.¹⁷¹ This lack of educational funding will force many beneficiaries who want to join the program to seek information from private sources, many of which may provide incomplete or inaccurate information.¹⁷²

This lack of education may cause beneficiaries to make improper enrollment choices. Moreover, insufficient educational efforts will likely cause many beneficiaries to forgo program enrollment during the open enrollment period, thereby costing these beneficiaries both possible prescription drug assistance from the federal government and a permanent, hefty late fee¹⁷³ for failing to enroll during the assigned open enrollment

¹⁶⁸ *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance, supra* note 106. The MMA encompasses hundreds of provisions, with 227 that required implementation by the end of 2004. *Id.* CMS must still clarify and implement the remaining provisions. *Id.* For example, low-income beneficiaries' enrollment procedures are still unclear. Marc Steinberg, *supra* note 76, at 4. The MMA assigns the administration of enrollment and re-determination for the low-income subsidy to both the Social Security Administration and state Medicaid agencies. *Id.* However, each organization's responsibilities are not yet specifically defined. *Id.*

¹⁶⁹ Moon, *supra* note 3, at 12.

¹⁷⁰ *Id.* The limited funding must not only educate fully functioning seniors, but also nursing home residents, many of whom suffer from dementia, Alzheimer's disease, or other brain disorders. See Robert Pear, *Medicare Changes May Cause Difficulty: Drugs May be Harder for Nursing Home Residents to Obtain*, COLUMBUS DISPATCH, Dec. 5, 2004, at 1.

¹⁷¹ Moon, *supra* note 3, at 12. Even if half of this funding is used for beneficiary education efforts, these resources would amount to just \$12 per beneficiary to provide comprehensive education on a new, complex outpatient prescription drug program. *Id.*

¹⁷² *Id.* Nursing homes can offer residents MMA information, but many will decline to do so because the nursing staff lacks understanding of the program's intricacies. See Pear, *supra* note 170.

¹⁷³ See discussion *supra* Part II.C.2.

period. This late fee will further discourage enrollment due to beneficiaries' inability or lack of desire to pay the resulting late enrollment premium increases.¹⁷⁴

ii. Largely Inadequate Plan and Drug "Choices."

Legislators enacted MMA as an alternative to a one-size-fits-all government entitlement program.¹⁷⁵ Policymakers forecast the plan's ability to drive down prescription drug costs due to competition between the many plan options the program requires in each geographical region.¹⁷⁶ In reality, the MMA only requires one PDP and one MAP to enter each geographical area.¹⁷⁷ The plan's fallback provision is only triggered if there is no private plan offering a prescription drug benefit in a geographical region.¹⁷⁸ Therefore, in cases where there is only one PDP and one MAP in a geographical region, the claimed competition amongst plans would not exist, suggesting that the resulting lower prescription drug prices in these regions would never materialize.

These fictional plan and drug choices may cause seniors to forgo enrollment in the plan for several reasons. First, if a particular Medicare beneficiary does not have a plan in his or her geographical region that covers his or her specific drugs, the beneficiary will probably decline to pay the premium to join an unattractive plan.¹⁷⁹ Additionally, because the MMA restricts a beneficiary's ability to change plans after the initial plan enrollment period,¹⁸⁰ if a beneficiary suspects that the plan may not cover his or her prescription drugs for the long term, the beneficiary may forgo program enrollment or simply drop out of the plan.¹⁸¹

¹⁷⁴ *Id.*

¹⁷⁵ *Medicare Prescription Drugs and Medicare Advantage Program Hearing Before the Senate Comm. on Finance, supra* note 106.

¹⁷⁶ *Id.*

¹⁷⁷ *See* discussion *supra* Part II.C.2.

¹⁷⁸ *Id.*

¹⁷⁹ Pear, *supra* note 124.

¹⁸⁰ *See* discussion *supra* Part II.C.2. An already-enrolled senior cannot change plans, even if their chosen plan decides not to cover medications the plan covered when the senior enrolled. Dallek, *supra* note 100, at 17.

¹⁸¹ Pear, *supra* note 124.

The MMA's endorsement of formularies¹⁸² may hinder beneficiaries' enrollment as well.¹⁸³ First, the MMA employs a confusing tiered cost sharing system, which specifically allows plan providers to change formularies, co-payments, and covered medications at any time without prior disclosure to enrollees.¹⁸⁴ Additionally, as stated above, plan providers use formularies that can limit the number of drugs covered in a specific category to just two.¹⁸⁵ In fact,

[a] formulary could comply with [model] guidelines while excluding coverage of 41 of the 50 drugs most commonly used by seniors . . . includ[ing] Lipitor and Zocor for high cholesterol, Norvasc for high blood pressure, Fosamax for osteoporosis, Celebrex and Vioxx for arthritis, Nexium for heartburn, Zoloft and Paxil for depression, and Allegra for allergies.¹⁸⁶

Moreover, the MMA allows private plan formularies to limit coverage to generic drugs only, thereby forcing beneficiaries and their physicians to select from a limited array of generic drugs, even if the generic formulas are not equivalent to the brand name drugs.¹⁸⁷ Worse, because a beneficiary cannot change plans, a plan may in essence force the beneficiary to switch medications in order to obtain any plan benefits.¹⁸⁸

¹⁸² Moon, *supra* note 3, at 8.

¹⁸³ Pear, *supra* note 124. Many believe that restrictive formularies may save money in the short term but will cost Medicare beneficiaries more over the long term, as the lack of drug choice will drive the need for hospital care, nursing home admissions, and doctors' visits. *Id.*

¹⁸⁴ Moon, *supra* note 3, at 8. Additionally, because the MMA does not establish clear guidance for those pharmacy plans supplying prescription drugs to nursing homes, many nursing home residents will pay higher co-payments and deductibles for using the nursing home's pharmacy if it is out of the beneficiary's pharmacy network. *See* Pear, *supra* note 170.

¹⁸⁵ Moon, *supra* note 3, at 8. Some speculate that the plan's formulary will include only drugs for which drug manufacturers offer large discounts. *Id.* This approach does not consider beneficiaries' best interests but instead focuses on a plan's profit maximization. *See id.* at 9.

¹⁸⁶ Pear, *supra* note 124.

¹⁸⁷ Moon, *supra* note 3, at 8.

¹⁸⁸ *Id.*

Finally, the MMA appeals process is confusing and cumbersome.¹⁸⁹ If a plan refuses to cover a beneficiary's prescription drug, a beneficiary must seek review by several governmental and independent review entities. If the review entities deny coverage, a beneficiary must then file suit in federal court.¹⁹⁰ These appeals requirements will likely cause Medicare beneficiaries considerable stress, forcing them to either forgo enrollment or drop out of the program.

Overall, the MMA outpatient prescription drug benefit contains largely inadequate plan and drug choice provisions that even on paper show little promise of significantly reducing prescription drug costs. Moreover, policymakers' claims that the law provides seniors with a program that allows beneficiaries to choose which drugs best suit their individual health needs are fictitious. If left unresolved, these problems will cause fewer Medicare beneficiaries to enroll in the program, creating a cycle whereby fewer private plans enter each market due to low enrollment and the resulting lack of potential for plan profitability. Fewer plans in each market will certainly lead to less competition and increased drug prices for all enrolled beneficiaries.

iii. The Drug Benefit Does Not Provide Meaningful Drug Coverage for Seniors Not Qualifying for Low-Income Assistance or Possessing Extraordinarily High Out-of-Pocket Drug Expenses.

The MMA's outpatient prescription drug plan assistance varies dramatically according to beneficiaries' income levels and drug spending habits.¹⁹¹ The plan provides substantial assistance for extremely low-income beneficiaries, only if these beneficiaries do not possess substantial assets.¹⁹² Indeed, the 8.7 million eligible low-income subsidy recipients

¹⁸⁹ See discussion *supra* Part II.C.2.

¹⁹⁰ See *id.*

¹⁹¹ Robert Pear and Walt Bogdanich, *Re-examining Medicare: Some Successful Models Ignored as Congress Works on Drug Bill*, N.Y. TIMES, Sept. 4, 2003. John C. Rother of the American Association of Retired People indicated, "the legislation was a 'real godsend' for people with low incomes or high drug expenses. 'But for many others, the benefits will be seen as inadequate.'" *Id.*

¹⁹² See discussion *supra* Part II.C.2; Pear and Bogdanich, *supra* note 191. Note that the CBO estimates that 1.8 million individuals eligible for benefits based solely on their income would not qualify for benefits under the asset test,

are projected to have out-of-pocket spending approximately 83% less than their projected 2006 prescription drug spending without an outpatient drug benefit.¹⁹³ The MMA outpatient drug plan directs substantial resources toward providing very low-income beneficiaries with affordable prescription drugs, and the plan effectively assists these beneficiaries.

Unfortunately, the MMA's outpatient prescription drug benefits are insufficient for those beneficiaries with moderate assets or those with incomes over 150% of the poverty level.¹⁹⁴ Because the drug benefit's provisions are uniform for all beneficiaries with incomes over 150% of the poverty level, those with incomes just slightly over the poverty level may find it difficult to pay the plan's premiums and cost sharing requirements.¹⁹⁵ For example, in 2006, a beneficiary with \$3000 in annual drug costs and an annual income of \$15,400 will still pay 12% of his or her income out-of-pocket for drugs, even after the beneficiary purchases Medicare prescription drug coverage.¹⁹⁶ The high out-of-pocket premiums and deductibles associated with the program may force those beneficiaries just above the poverty line to forgo enrolling in the program simply because they cannot afford to do so.¹⁹⁷

While beneficiaries not designated low-income will have out-of-pocket drug costs 28% less, on average, than without the benefit,¹⁹⁸ 24%

and 700,000 beneficiaries would receive lower subsidies because of their failure to meet asset requirements. Moon, *supra* note 3, at 7.

¹⁹³ Mays et al., *supra* note 4, at 19. Each of the 6.4 million dual eligible will average \$94 annually in out-of-pocket prescription drug spending, \$263 less than beneficiary spending estimates without the MMA outpatient prescription drug benefit. *Id.* at 9-10. Those earning less than 135% of the federal poverty line will average \$153 each in out-of-pocket spending, and those with income between 135% and 149% of the federal poverty line will average \$406 in out-of-pocket spending. *Id.* These two groups will see an average savings of \$1,400 annually per beneficiary. *Id.*

¹⁹⁴ Moon, *supra* note 3, at 5.

¹⁹⁵ *Id.* at 5.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ Mays et al., *supra* note 4, at 19. This savings estimate does not account for the monthly premiums beneficiaries pay. *Id.* Therefore, beneficiaries' out-of-pocket savings is actually less than 28%, amounting to an average of \$1081 in annual out-of-pocket spending per beneficiary. *Id.* at 10. These savings are comparable to those garnered with the Medicare-approved prescription drug discount cards. *See* discussion *supra* Part II.C.1.

of all outpatient prescription drug plan participants are projected to have out-of-pocket prescription drug costs that exceed the plan's initial coverage limit of \$2,250 in 2006.¹⁹⁹ Yet, less than half of this group is expected to qualify for the plan's \$5,100 catastrophic limit in 2006,²⁰⁰ even though 75% of beneficiaries in this group have incomes below 300% of the poverty level.²⁰¹

In addition to the existing financial strain placed on those Medicare beneficiaries not qualifying for low-income benefits, the law requires the drug benefit's cost sharing to be indexed annually, proportional to the increase in the benefit's cost.²⁰² Indeed, the projected \$3600 in out-of-pocket costs that a beneficiary over 150% of the poverty level must pay in 2006 to obtain catastrophic coverage is expected to rise 78% to \$6400 in 2013, while a Medicare beneficiary's monetary benefits are expected to rise at about half of that rate over the same period. Thus, the plan's annual cost index adjustment will make a beneficiary's participation in the plan increasingly costly and therefore less likely.²⁰³

The MMA's drug cost negotiation rules also deny Medicare beneficiaries the full potential of a government-sponsored prescription drug program. As stated above, the MMA makes it illegal for Medicare to negotiate drug prices on behalf of its beneficiaries.²⁰⁴ The rules also

¹⁹⁹ Mays et al., *supra* note 4, at 12.

²⁰⁰ *Id.* Only 11% of plan beneficiaries will qualify for the catastrophic limit. *Id.* This is due in large part to Congress' insistence that the Medicare plan require beneficiaries to pay all prescription drug costs, instead of allowing supplemental insurance providers or health plans to fill the benefit's gap. Moon, *supra* note 3, at 4. This provision helps to maintain the plan's total costs by preventing beneficiaries from qualifying for the plan's catastrophic benefits. *Id.*

²⁰¹ Mays et al., *supra* note 4, at 12.

²⁰² Moon, *supra* note 3, at 6.

²⁰³ *Id.*

²⁰⁴ Melissa Ganz, Comment, *The Medicare Prescription Drug Improvement & Modernization Act of 2003: Are We Playing the Lottery with Healthcare Reform?* 2004 DUKE L. & TECH. REV. 11. During the 2002 election cycle, pharmaceutical companies, health care professionals, and the insurance industry donated over \$109 million to candidates for federal offices. BARRY R. FURROW ET AL., *THE LAW OF HEALTHCARE ORGANIZATION AND FINANCE* 135 (5th ed. 2004). Indeed, "[t]he 2003 Medicare Modernization Act, which established a \$400 billion Medicare drug program while barring CMS from negotiating drug prices . . . demonstrates the effectiveness of these lobbying efforts." *Id.*

establish that a government fallback plan cannot take advantage of its lower administrative costs compared with private plans.²⁰⁵ Although the rationale is “to promote competition,” the plan promotes a privately controlled system where the drug companies establish discounts and formularies based on what they deem proper.²⁰⁶

As a final blow to Medicare beneficiaries’ ability to obtain meaningful prescription drug cost assistance, the program awards private plans substantial funds to participate in the Medicare program.²⁰⁷ Hidden in the details of the 678-page bill is the establishment of a \$10 billion fund to encourage private plans to participate in the Medicare program.²⁰⁸ In addition to this language, the MMA authorizes private plans to administer the program²⁰⁹ although studies show that “Medicare spends two cents on the dollar [for] administrative costs, [while] private health insurance companies spend up to twenty-five cents on the dollar in small group markets and five and a half cents on the dollar in large-group markets for administrative costs.”²¹⁰

Thus, by design, the MMA does not dedicate ample resources to those beneficiaries above 150% of the poverty level. In some instances, the beneficiary will obtain only minimal drug cost relief even after enrollment in the Medicare prescription drug benefit. This minimal benefit will decline as the prescription drug premium is indexed according to the actual cost of the drug plan. Most disturbing is that not only does the MMA intentionally place a large financial burden on Medicare beneficiaries but it also allows private insurance plan providers to garner immense profits from these beneficiaries--the very group the program was designed to assist. Indeed, the windfall that drug companies receive under the plan “has caused many to wonder if [seniors are] paying twice for [the same benefits,] once as taxpayers and then again as consumers.”²¹¹

²⁰⁵ Moon, *supra* note 3, at 8.

²⁰⁶ Ganz, *supra* note 204.

²⁰⁷ Oberlander, *supra* note 33, at 1134.

²⁰⁸ *Id.* This provision essentially subsidizes a private plan’s operating costs if the plan enters the Medicare program. *Id.*

²⁰⁹ Moon, *supra* note 3, at 9.

²¹⁰ FURROW ET AL., *supra* note 204, at 133.

²¹¹ Ganz, *supra* note 204.

IV. PUBLIC POLICY SOLUTIONS TO PROVIDE ALL MEDICARE-ELIGIBLE SENIORS WITH SUBSTANTIAL PRESCRIPTION DRUG COVERAGE WHILE SUSTAINING MEDICARE'S FISCAL HEALTH.

Admittedly, implementing a Medicare outpatient prescription drug benefit that provides all Medicare beneficiaries with meaningful prescription drug cost assistance is no easy task. Indeed,

[we must take care] to ensure that any potential expansion of the program be balanced with other programmatic reforms so that we do not worsen Medicare's existing financial imbalances. The program needs to include adequate fiscal incentives to control costs, and benefits should be carefully targeted to meet genuine needs while remaining affordable.²¹²

The following section proposes changes that policymakers should make to the current MMA drug program to create a more significant and equitable benefit for all beneficiaries while keeping Medicare program costs reasonable. These recommendations include a mandatory enrollment requirement for beneficiaries, centralized administration of the program, and mandatory governmental price negotiation.

A. MANDATE MEDICARE BENEFICIARIES' PLAN ENROLLMENT TO ENCOURAGE DRUG COMPANIES TO NEGOTIATE DEEPER PRESCRIPTION DRUG DISCOUNTS.

As noted above, to encourage drug companies to negotiate deeper prescription drug discounts, the Medicare prescription drug plan must include mandatory enrollment. Some argue that a mandatory participation requirement would cause the plan to fail, as President Reagan's mandatory enrollment Medicare drug plan did in the late 1980's.²¹³ However, President Reagan's mandatory participation drug program failed not because the program was mandatory but because: (1) the plan imposed a supplemental tax on higher-income beneficiaries; and (2) many seniors

²¹² *Medicare: Financial Outlook Poses Challenges for Sustaining Program and Adding Drug Coverage Before the House Comm. on Ways and Means, supra note 2, at 1, 16.*

²¹³ *See* MCCA background discussion *supra* Part II.A.

had more substantial employee-provided prescription drug coverage through other sources.²¹⁴

Neither of those factors exists today. The MMA prescription drug benefit plan does not impose a higher rate on higher income beneficiaries.²¹⁵ With the exception of low-income beneficiaries, all beneficiaries pay the same deductibles and cost sharing for the program.²¹⁶ Additionally, studies show that employer-provided prescription drug benefits for employees and retirees have fallen off dramatically in the last five years.²¹⁷

Today, because so many Medicare beneficiaries lack employer-provided prescription drug coverage, beneficiaries are likely to support a Medicare prescription drug benefit, even if enrollment is mandatory. Forced enrollment guarantees that drug companies will negotiate discount prescription drug prices or risk having their drugs left out of the Medicare outpatient prescription drug program. Mandatory enrollment also ensures that seniors will not suffer draconian penalties for tardy enrollment in the program.²¹⁸

B. CENTRALIZE THE PLAN'S ADMINISTRATION.

To eliminate unnecessary overhead costs and provide increased prescription drug benefits to all Medicare-eligible seniors, policymakers should eliminate the MMA's use of private prescription drug plan providers and instead implement a single Medicare-sponsored and

²¹⁴ Oliver et al., *supra* note 3, at 301.

²¹⁵ See discussion *supra* Part.II.C.2.

²¹⁶ *Id.*

²¹⁷ See generally Bruce Stuart et al., *Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years*, HEALTH AFFAIRS Web Exclusive, Jul. 23, 2003, at W3-334, <http://content.healthaffairs.org/webexclusives> (follow "2003" hyperlink; then follow "Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years" PDF hyperlink). This study found that the proportion of Medicare beneficiaries ages sixty-five to sixty-nine with employer sponsored drug coverage fell from 46% in 1996 to 39% in 2000. *Id.* at W3-334. The employer-provided benefits are quickly disappearing because increasing healthcare and prescription drug costs make it impossible for employers to provide retirees with meaningful prescription drug benefits at a reasonable cost to both. *Id.* at W3-340.

²¹⁸ See discussion *supra* Part II.C.2.

administered outpatient prescription drug program. Although many policymakers claim that private providers' administration of the MMA outpatient prescription drug program will cost less, experience and recent reports suggest otherwise.²¹⁹ In fact, the Congressional Budget Office recently found that Medicare spends between \$650 and \$750 more per year per enrollee for beneficiaries who enroll in preferred provider organizations as opposed to the traditional Medicare system.²²⁰

In addition to direct cost savings, allowing the federal government to administer a single Medicare outpatient prescription drug program has other benefits. Research indicates that Medicare beneficiaries are more likely to participate in and support a government-run plan.²²¹ With just one plan, beneficiaries will not be faced with the decision regarding which plan to join. This structure will enable Medicare to create an outpatient prescription drug plan that is used by more Medicare beneficiaries with lower administrative costs than through a private provider system. Those savings can then be reinvested into a centralized plan's prescription drug program to provide Medicare beneficiaries with additional prescription drug cost assistance.

C. MANDATE PRESCRIPTION DRUG PRICE NEGOTIATION.

In addition to enacting mandatory enrollment and centralized plan administration requirements, policymakers must also amend the MMA to allow the federal government to negotiate drug prices with prescription

²¹⁹ Robert Pear, *Inquiry on Medicare Finds Improper Limits on Choices*, N.Y. TIMES, Sept. 28, 2004, at A15. See also Gardiner Harris, *Citing Higher Costs, U.S. Plans Record Rise in Medicare Premium*, N.Y. TIMES, Sept. 4, 2004, at A1 (stating that due to higher administrative costs, private plans are more costly than regular Medicare).

²²⁰ Pear, *supra* note 219. This finding was contrary to Medicare officials' predictions. *Id.*

²²¹ Oliver et al., *supra* note 4, at 308. Indeed, "[f]ocus groups conducted by Republican and Democratic polling firms confirmed that . . . most Medicare beneficiaries preferred that prescription drug coverage be administered by the Federal Medicare program rather than by private health plans or state run programs." *Id.*

drug companies.²²² Many analysts project that government price negotiation could eliminate the MMA's tiered cost sharing system.²²³

Most industrialized countries' prescription drug costs are substantially lower than the United States'.²²⁴ If negotiated drug prices resulted in a 45% reduction, the MMA's donut hole would close without additional governmental funding for the plan.²²⁵ With the donut hole closed, savings to beneficiaries under the MMA outpatient prescription drug benefit would be proportionately larger, ranging from \$794 to \$1,153 per beneficiary per year, with 25% or more of beneficiaries reducing out-of-pocket spending by at least \$1000.²²⁶

While some critics argue that government-based prescription drug cost negotiation limits both seniors' choice regarding drug benefits and access to drugs, the Veteran's Administration (hereinafter "VA") prescription drug program offers a powerful example of a government agency that successfully negotiates prescription drug costs on veterans' behalf.²²⁷ The negotiation program employs doctors and pharmacists to analyze, research, and establish a list of preferred drugs.²²⁸ The program then obtains discounts through purchasing arrangements for generic and name brand drugs.²²⁹ In 2000, the National Academy of Sciences found that the VA approach saved the program more than \$100 million in 1998 and 1999 without adverse effects on quality.²³⁰

CMS could model its prescription drug negotiation program after the VA's approach, employing a nonpartisan commission to decide which drugs should be covered and negotiated, made up of economists, health

²²² Ganz, *supra* note 204. As stated above, the current version of MMA makes government negotiation of prescription drug prices illegal. *Id.*

²²³ See discussion *supra* Part II.C.2.

²²⁴ Anderson et al., *supra* note 71.

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ Pear and Bogdanich, *supra* note 191. In fact, "[w]ielding its power as one of the largest purchasers of medications in the United States, the [VA] has made it possible for millions of beneficiaries to pay just \$7 for up to a 30-day prescription." *Id.* The VA program owes its success to its willingness to use its buying power to negotiate prescription drug prices. *Id.*

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ *Id.*

care professionals, and industry representatives. The commission would make the program's drug coverage decisions based on the drug's effectiveness over already covered drugs, the availability of a generic version of the drug, and the drug company's willingness to negotiate a drug's price with Medicare.

If the commission decided not to cover the drug as part of the MMA formulary, the government could still negotiate a reduced rate for the drug's purchase, but the Medicare beneficiary would be responsible for paying the fixed, negotiated cost for the drug. This would guarantee flexibility in the plan so that seniors were not required to use drugs with adverse side effects or pay high costs for drugs not covered under the Medicare outpatient prescription drug plan. Moreover, with the 41 million beneficiaries that CMS would bring to the bargaining table, it is unlikely that a drug company would refuse to negotiate lower prices with Medicare and forgo such an immense market. Government negotiation would give seniors access to more brands of drugs at more affordable prices, rather than less of either.

The above discussion argues that policymakers must amend MMA to allow the federal government to negotiate prescription drug costs with pharmaceutical companies. These amendments would allow the MMA outpatient prescription drug plan to provide meaningful prescription drug benefits to all Medicare beneficiaries. As illustrated by the VA experience, government negotiation of prescription drug costs under the MMA could lead to substantially lower program costs and an elimination of the plan's tiered cost-sharing system.

V. CONCLUSION

The current MMA should be viewed as the first step toward providing Medicare beneficiaries with meaningful prescription drug coverage. As constructed, the law has serious potential problems that need to be resolved, including the plan's failure to: (1) educate seniors about the benefit; and (2) provide significant benefits to those beneficiaries who neither qualify for the program's low-income benefits nor have extraordinarily high prescription drug costs. In order to provide meaningful prescription drug benefits to all Medicare beneficiaries, Congress must act.

First, to inform beneficiaries about the outpatient prescription drug benefit, Congress must fully fund beneficiary education efforts. This will help seniors to take advantage of the program's financial benefits. Second, Congress should require all Medicare beneficiaries to participate

in the outpatient prescription drug program. This will maintain the program's balance of healthy and sick beneficiaries, which will help keep program costs stable. Moreover, mandatory enrollment will ensure that seniors advocate for continued program funding. Third, to control the program's administrative costs, policymakers should place the plan under the federal government's supervision. Finally, to keep costs reasonable and provide Medicare beneficiaries with additional drug cost assistance, policymakers should amend the law to allow the federal government to negotiate prescription drug prices. These legislative enactments will provide more comprehensive prescription drug benefits to all Medicare recipients while keeping Medicare beneficiaries satisfied and the Medicare program solvent.