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An Rx for the Modification of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Toward a Reform with Results

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An Rx for the Modification of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Toward a Reform with Results

Daniel Katz and Monica Deshpande*

The advent of modern medicine has increased the quality of available health care services dramatically. The use of outpatient prescription drugs has allowed today’s patients to live longer, more productive lives. However, the shift from invasive inpatient procedures to outpatient pharmaceuticals has come at a price. There has been a significant increase in demand, prices, per capita expenses, and total expenditures for these prescription drugs.

Moreover, the burden of these sizeable expenses has not been distributed uniformly across the population. In particular, senior citizens have greater health care needs and, therefore, are most likely to incur significant

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1. THE NAT’L INST. FOR HEALTH CARE MGMT. FOUND., PRESCRIPTION DRUG EXPENDITURES IN 2001: ANOTHER YEAR OF ESCALATING COSTS 7, available at http://www.nihcm.org/spending2001.pdf (May 6, 2002). In 1992, pharmacists filled 1.9 billion prescriptions while just eight years later, in 2000, they filled over 3.1 billion. This study found a 63% increase in the number of prescriptions filled in the United States. Figures are for prescriptions dispensed in retail outlets.

2. Id. at 8. Between 2000 and 2001, the average price of a prescription drug increased over 10%.


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prescription drug costs. One recent study found adults over the age of sixty-five experienced annual "out-of-pocket" pharmaceutical expenditures more than double that of the average adult under the age of sixty-five.

Medicare, the public health insurance system for older Americans, has struggled to keep pace with these expenditure trends of modern medicine. For example, prior to recent legislation, traditional fee-for-service (FFS) Medicare lacked any significant form of an outpatient prescription drug benefit. This lack of coverage had a detrimental impact on seniors who increasingly relied upon medications but were unable to acquire necessary supplementary drug coverage. Some seniors lacking coverage chose to travel abroad to purchase their medications, while others without such recourse faced the difficult choice between spending their limited financial resources on medication, or on food or other essentials.

In reaction to this problem, various policymakers touted plans designed to relieve seniors' potential hardship by reforming Medicare to include a prescription drug benefit. Following the midterm elections of 2002, President George W. Bush formally introduced a plan for Medicare reform during his 2003 State of the Union Address. Strenuous debate surrounded

5. Id.
6. Id. In 2000, outpatient prescription expenditures for those over the age of sixty-five averaged $1,102 as compared to $485 for the average adult under the age of sixty-five. Similar findings exist for the years immediately prior to 2000.
13. Rak, supra note 9, at 491-504.
the details of his proposal as Congress considered it along with a wide variety of competing Medicare reform proposals. After months of deliberation, the conference committee reached agreement and the House and Senate approved a final version of the bill. On December 8, 2003, President Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MPDIMA).

Beginning in calendar year 2006, MPDIMA adds Part D to Medicare, establishing a new voluntary prescription drug benefit through a privately-offered prescription drug program. MPDIMA also allows seniors to opt out of traditional Medicare by enrolling in Medicare Advantage (MA), a managed care program with integrated drug coverage. A significant number of low-income seniors that lack the resources to purchase supplementary coverage and are ineligible for Medicaid may now receive substantial benefits from this legislation. However, despite the new benefits MPDIMA creates, a more thoughtfully-crafted version of the legislation could provide more expansive, less expensive coverage for a greater number of Medicare-eligible seniors.

This article begins with a brief overview of the Medicare system prior to the passage of MPDIMA. Next, it highlights several key sections of the legislation and outlines specific areas that Congress could modify to provide greater value to both taxpayers and Medicare enrollees. Finally, the article discusses cost-containment strategies to fund the effort to provide a more substantial and cost-effective Medicare prescription drug benefit.

18. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C.A. § 1395 (West 2004) [hereinafter MPDIMA]. This act was recently codified and was only available in the annotated version at press time.
19. Id. § 101.
20. Id. § 1396. The Medicaid system leaves specific eligibility decisions to the respective states. However, the statute sets forth the minimum coverage boundaries.
21. See id. § 121(a). Currently, all state Medicaid programs offer a prescription drug benefit to seniors who meet individual state eligibility requirements.
I. THE MEDICARE SYSTEM PRIOR TO MPDIMA

As noted above, Medicare is a public insurance program that provides health care coverage to most of America’s seniors. To be eligible, an individual must be a citizen or resident alien and at least sixty-five years of age. The Medicare system is financed through general tax revenues and employer and employee contributions. Therefore, a potential recipient must make contributions to the system in the form of payroll taxes for a requisite number of years in order to be eligible for the program.

Prior to MPDIMA, the Medicare program consisted of Parts A, B, and C. Part A primarily covered inpatient hospitalization, while Part B covered outpatient care and physician services. Historically, traditional fee-for-service (FFS) Medicare, Parts A and B, failed to cover the entire range of available medical services. Thus, prior to MPDIMA, Medicare permitted enrollees to purchase supplemental benefits plans called Medigap. Medigap provided seniors with extra coverage for additional services, such as prescription drugs.

In addition to Medigap, Part C (Medicare + Choice) allowed seniors to opt out of traditional FFS Medicare through enrollment in privately-

24. MPDIMA, supra note 18, § 1395i-2(a)(3).
25. Id. § 1395i-2(a)(1).
26. See id. § 1395i(a)(1)-(2) (Medicare Part A affords coverage to any citizen and his or her spouse who has either provided a sufficient amount of payroll tax contribution or is otherwise eligible to receive a monthly Social Security benefit. It allows those not eligible through any other means to “buy in” to Medicare coverage through the payment of an enrollment premium).
27. MEDICARE FACT SHEET, supra note 8.
28. MPDIMA, supra note 18, § 1395d-(a)(1). Payroll tax contributions to the Medicare trust fund primarily finance Part A. Id.
29. MPDIMA, supra note 18, § 1395k(a). General tax revenues and enrollee co-payments primarily finance Part B. Id. § 1395j.
31. MPDIMA, supra note 18, § 1395ss.
32. Id. Services available through Medigap varied by provider, some Medigap plans did provide drug coverage. However, some seniors found these plans either unaffordable or altogether unavailable. See THE LEWIN GROUP, AARP PUB. POL’Y INST., RESTRICTING UNDERWRITING AND PREMIUM RATING PRACTICES IN THE MEDIGAP MKT.: THE EXPERIENCE OF THREE STATES 11-14, available at http://research.aarp.org/health/2001_01_medigap.pdf (Jan. 2001).
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operated managed care plans. Some Part C enrollees received additional benefits not included in traditional FFS Medicare, including prescription drug coverage. However, Part C managed care plans typically required patients to choose a primary care physician from a list of plan-approved doctors and often mandated program approval in order to see a specialist. Furthermore, since many of the managed care plans faced financial difficulties, some plan operators chose to discontinue coverage in certain geographic markets, leaving many seniors without Part C coverage.

<table>
<thead>
<tr>
<th>Medicare Coverage Options</th>
<th>Description</th>
<th>Available Prior to MPDIMA</th>
<th>After MPDIMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part A</td>
<td>Hospital Insurance Program</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Parts A + B (Traditional FFS Medicare)</td>
<td>Hospital Insurance Program and Supplementary Medical Insurance</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Parts A +B +Medigap</td>
<td>Traditional FFS Medicare with choice of Medigap supplemental coverage</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Part C (Medicare + Choice)</td>
<td>Managed Care</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Medicare Advantage</td>
<td>Managed Care</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Parts A +B +D</td>
<td>Traditional FFS Medicare with Prescription Drug Plan Benefit</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

II. OVERVIEW OF MPDIMA DRUG PLANS: THE PART D PRESCRIPTION DRUG PLAN AND MEDICARE ADVANTAGE

A. Part D Prescription Drug Plans

President Bush has maintained that MPDIMA provides enrollees

33. MPDIMA, supra note 18, § 1395w-21(a).
34. MPDIMA, supra note 18, § 1395(a)(1)(B).
maximum flexibility by allowing them to choose their optimal plan.\(^{37}\) Starting in 2006, those qualified to enroll in Medicare Parts A and B will also be eligible to enroll in a Medicare Part D prescription drug plan (PDP).\(^{38}\) MPDIMA requires every insurance provider to furnish either the statutorily-defined coverage plan or its actuarial equivalent.\(^{39}\) Alternatively, MPDIMA allows enrollees to choose a Medicare Advantage managed care plan that covers the range of services mirroring the aggregation of Parts A, B, and D.\(^{40}\)

Pursuant to the legislation, standard coverage under a Part D PDP features a number of premiums, co-payments and coverage gaps.\(^{41}\) The monthly premium for Part D will be approximately $35 in 2006, and may rise to approximately $58 per month by 2013.\(^{42}\) The standard coverage under Part D also requires a separate annual deductible of $250.\(^{43}\) Furthermore, it requires an enrollee to make a 25% co-payment with the balance covered by the plan for annual true “out-of-pocket” prescription drug expenditures between $250 and $2,250.\(^{44}\) However, for prescription drug true out-of-pocket expenditures between $2,250 and $3,600, the standard coverage features a “donut hole” coverage gap requiring an

37. Press Release, President George W. Bush, Keeping Our Promise to America's Seniors: President Bush Signs the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Dec. 8, 2003), available at http://www.whitehouse.gov/infocus/medicare/ [hereinafter President Signs Medicare Act]. President Bush stated “[E]very senior needs to know: if you don’t want to change your current coverage, you don’t have to change. You’re the one in charge. If you want to keep your Medicare the way it is, along with the new prescription benefit, that is your right . . . . For the seniors of America, more choices and more control will mean better health care.” Id.

38. MPDIMA, supra note 18, § 1395w-101.

39. Id. § 1395w-102(a). Under MPDIMA, if adequate private market options fail to materialize then government officials may supplement regions that are not adequately covered by the private market with additional coverage to ensure that each geographic region features a minimum of two prescription drug plans. Id. § 1395w-103(a). The Secretary of Health and Human Services is required to ensure that each Part D eligible has at least two qualifying plans within a given geographic area. The Secretary must allow such individual the opportunity to enroll in a fallback plan if the region fails to meet the two plan requirement.

40. Id. § 1395w-101.

41. Id. § 1395w-102(a)(2)(A)(I).

42. JOINT ECON. COMM. DEMOCRATS, THE NEW MEDICARE PRESCRIPTION DRUG ACT: INDEXING EFFECT ERODES BENEFIT 2 (2004) [hereinafter JOINT ECON. COMM. REP.]. This brief cites a Congressional Budget Office (CBO) study which projects that the average premium for a Part D PDP plan will be $35 per month in 2006. Furthermore, the CBO study projects that over the next decade per capita drug spending will increase by about 8.5% annually. Thus, taking these two findings together, the CBO estimates monthly premium will reach $58 by 2013 since this payment is not indexed for inflation.

43. MPDIMA, supra note 18, § 1395w-102.

44. Id.
enrollee to pay all of his or her prescription drug costs. Once total annual expenditures reach $5,100, whereby corresponding true out-of-pocket expenditures reach $3,600, the standard coverage may be subject to a catastrophic cap, which covers all additional costs except for a nominal co-payment per prescription.

**TABLE 2: ILLUSTRATION OF THE “DONUT HOLE” COVERAGE GAP**

<table>
<thead>
<tr>
<th>Deductible</th>
<th>Limited Coverage</th>
<th>No Coverage</th>
<th>Catastrophic Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>75%</td>
<td>100%</td>
<td>95%</td>
</tr>
<tr>
<td>25%</td>
<td>5%</td>
<td>“Donut Hole”</td>
<td>5%</td>
</tr>
<tr>
<td>$0</td>
<td>$250</td>
<td>$2,250</td>
<td>$5,100</td>
</tr>
</tbody>
</table>

To assist low-income seniors, MPDIMA also provides a subsidy that either reduces or eliminates a recipient’s annual deductible, monthly Part D

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45. *Id.*

46. *Id.* The size of the donut hole coverage gap is expected to grow since its upper and lower bounds are not indexed for inflation.

47. *Id.* § 1395w-102(b)(4)(A)(i). This nominal co-payment is equal to the greater of 5% of the prescription cost or the flat price of $2 for a multiple source drug as defined in Pub. L. No. § 101-1860D-1(a)(4)(A)(1)(I) and $5 for any other type of prescription.

48. MPDIMA, *supra* note 18, § 1395w-114(a)(1). Assistance under this section is available on a sliding scale with the maximum income for eligibility of 150% of the federal poverty line. *Id.* § 1395w-114(a)(2)(A).
premium, and out-of-pocket expenses. Since MPDIMA contains a restriction on the purchase of new Medigap policies that provide prescription drug coverage, this subsidy may prove particularly necessary for low-income seniors.

B. Medicare Advantage

As an alternative to Parts A, B, and D, MPDIMA allows seniors to leave traditional Medicare and enroll in Medicare Advantage (MA). MA is a comprehensive managed care program analogous to the former Medicare Part C (Medicare + Choice) program. To ensure managed care plan participation in MA, MPDIMA has increased aggregate payments to these plans by $1.3 billion for 2004 and 2005. These increased payments grant MA plans greater flexibility in their offerings. Thus, MA plans will not only provide the same range of services available to recipients collectively enrolled in Parts A, B and D, but also may offer additional benefits not featured in Parts A, B, and D. Some of these additional benefits include reduced cost sharing, dental, and vision services.

III. OVERVIEW OF PROBLEMS WITH MPDIMA’S DRUG PLAN DESIGN

While both Medicare Part D prescription drug plans and the Medicare Advantage (MA) program will offer prescription drug coverage to a significant number of seniors, a more carefully devised statutory design could have enhanced public value for both Medicare recipients and taxpayers. Specifically, Part D coverage set forth in MPDIMA is inefficient because it fails to dovetail with current retiree drug programs.

49. Id. § 1395w-114.
50. Id. § 1395ss. This provision prohibits the sale, issuance, and renewal of new Medigap policies containing prescription drug coverage. Yet, Part D eligibles are permitted to renew policies issued before Jan. 1, 2006, so long they are not concurrently enrolled in Part D. Id.
51. Id. § 1395w-101(a)(1)(A).
52. Id. MA is similar to the Part C (Medicare + Choice) program. Yet, MA features greater per patient reimbursement and requires plan operators to provide drug coverage. Part C plus choice only authorized plan operators to provide drug coverage. THE HENRY J. KAISER FAMILY FOUND., MEDICARE FACT SHEET: MEDICARE ADVANTAGE, available at www.kff.org/medicare/2052-07.cfm (Mar. 2004) [hereinafter MA FACT SHEET].
53. Id.
54. Id.
55. PAULETTE MORGAN & HINDA CHAIKIND, CONG. RESEARCH SERV., MEDICARE ADVANTAGE: WHAT DOES IT MEAN TO PRIVATE PLANS CURRENTLY SERVING MEDICARE BENEFICIARIES, CRS Report RS21761, at 2-3 (Mar. 8, 2004).
56. Id.
57. Park, supra note 22.
arguably creating the need for the legislation’s expansive employer subsidies.  

Furthermore, MPDIMA disadvantages “dual eligibles,” which are seniors qualifying for both Medicare and Medicaid due to their age and indigent economic status. Under MPDIMA, these seniors face much higher co-payments than they currently pay under state Medicaid programs. Additionally, the limited drug formulary requirements under MPDIMA may leave some seniors without coverage for certain brands of medication.

MPDIMA creates an asymmetry in bargaining power between enrollees and plan operators. Historically, beneficiaries had the option to either enroll or decline a Medicare managed care plan at any time during the year. However, starting in 2006, beneficiaries enrolled in MA plans can only switch plans or disenroll from the program once per year, during a specific time period.

Furthermore, MPDIMA’s deference towards managed care may substantially increase the costs of providing a drug benefit. For example, 2004 Medicare payments to managed care plans were on average 107% of the cost to cover similar benefits under traditional fee-for-service (FFS) Medicare; in some areas, payments were 132% of FFS costs. In addition to its increased costs, many seniors have expressed strong antipathy towards the managed care programs offered through Medicare. In response to this concern, President Bush has noted that under MPDIMA seniors can keep their traditional Medicare, enroll in prescription drug plans, and forgo entrance into managed care. While his assertion may be technically accurate, it does not adequately acknowledge the full range of choices that seniors could face. The structure of MPDIMA presents seniors with a

58. MPDIMA, supra note 18, § 1395w-132.
61. ISSUES FOR DUAL ELIGIBLES, supra note 60.
62. MA FACT SHEET, supra note 52.
63. Id.
64. Id. at 2.
66. President Signs Medicare Bill, supra note 37.
choice between a Part D plan featuring a substantial coverage gap and an MA managed care program with such large reimbursement payments that it can operate less efficiently, yet provide more attractive cost-sharing options. Therefore, despite the President’s desire to provide increased options to seniors, the MPDIMA legislation statutorily stacks incentives in favor of managed care and thereby fails to produce the desired outcome.

A. Revising the Definition of “Out-of-Pocket Costs”

The existence of such a large coverage gap in Part D creates significant concerns. Nonetheless, budgetary and political limitations may preclude complete drug coverage for the entire Medicare-eligible population. In light of this financial strain, steps should be taken to minimize the effects of the donut hole coverage gap. First, while it may increase the cost of this legislation, modifying the definition of “out-of-pocket” expenses could represent a significant step toward closing the legislation’s coverage gap. As noted earlier, the Part D prescription drug plan (PDP) provides the most comprehensive coverage, but only after a beneficiary has incurred $3,600 in out-of-pocket costs. Furthermore, MPDIMA’s definition of “out-of-pocket cost” excludes virtually all third-party expenditures, including employer retiree plan drug expenditures.

Currently, the legislation provides employers with a substantial incentive to maintain existing retiree drug coverage. However, the decision to ignore employer outlays as an out-of-pocket cost arguably marginalizes this incentive. Congress could consider retiree prescription drug plans as a

68. See President Signs Medicare Act, supra note 37.
70. NAT’L BIPARTISAN COMM’N ON THE FUTURE OF MEDICARE, FINAL COMM. REPORT: BUILDING A BETTER MEDICARE FOR TODAY AND TOMORROW, available at http://medicare.commission.gov/medicare/bbmtt31599.htm (Mar. 16, 1999). The framework detailed in the Commission’s report outlined much less than complete prescription drug coverage for all seniors. Id. The decision by the commission, together with fiscal constraints, precluded the successful proposal for universal Medicare drug coverage.
71. MPDIMA, supra note 18, § 1395w-102. The out-of-pocket expenditure level necessary to trigger MPDIMA’s most holistic coverage is $3600 in 2006 and this out-of-pocket expense will grow in subsequent years since this level is not indexed for inflation.
72. Id. § 1395w-102(b)(4)(C)(i). The current provision creates a hard or true out-of-pocket cost.
73. Id. § 1395w-132.
74. Id. § 1395w-102(b)(4)(C)(ii). This subsection prevents third-party employer expenditures from qualifying as an “out-of-pocket cost” for purposes of the catastrophic cap. Thus, employer or other third-party expenditures do not close the donut hole of coverage.
form of deferred compensation. Such expenditures, while technically third-party in nature, could have counted as an out-of-pocket cost for the purposes of satisfying the catastrophic cap.

By permitting the inclusion of employer spending within its statutory definition, the legislation could have created a more efficient system. Employers currently supplying retiree coverage could have capped their current prescription drug benefit spending at the MPDIMA catastrophic cap. By doing so, employers would have been able to cover most of their employee’s maximum annual financial exposure. Such a public-private partnership could have potentially prevented a significant number of seniors from being exposed to the substantial out-of-pocket expenses that the existing coverage donut hole creates.

Instead, at best, the current legislation presents incomplete incentives to employers. While the legislation may encourage some employers to maintain prescription drug coverage, the subsidy may also entice employers to provide only nominal coverage. Furthermore, because of the current definition of “out-of-pocket cost,” the legislation may require enrollees to face premiums, co-payments and the coverage gap, once seniors exhaust their private-employer coverage plan.

Moreover, both the subsidy and the statutory definition of “out-of-pocket cost” add significant expense to this legislation and only provide a marginal benefit. Thus, to create a more efficient and equitable Medicare prescription drug benefit, Congress should re-craft MPDIMA to provide a more expansive definition of “out-of-pocket cost.”

B. Concerns Regarding Cost-Sharing for Medicare-Medicaid “Dual Eligibles”

This legislation’s impact upon dual eligibles provides yet another concern. Pursuant to MPDIMA and starting in 2006, Medicare will replace Medicaid as the primary provider of prescription drug coverage for dual eligibles. If an available Medicare sub-program provides a particular type of benefit, then it is deemed to be its exclusive provider. Thus, Medicaid acts as a programmatic, rather than a benefit, gap filler.

75. See id.
76. See MPDIMA, supra note 18, § 1395w-102(b)(4)(C)(ii) (2004). Employers may only have an incentive to provide the minimum coverage necessary to qualify for the subsidy.
77. Id. § 1395w-102.
78. DUAL ELIGIBLE DEFINITION, supra note 59.
79. MPDIMA, supra note 18, § 1396u-5(a)(3).
seniors. MPDIMA does not require plan operators to provide coverage for the same drugs dual eligibles received under the state Medicaid programs. MPDIMA will now require dual eligibles currently residing in states with generous Medicaid benefits to make a statutorily-mandated co-payment for each of their prescriptions. Currently, most state Medicaid programs have either very nominal co-payments or no co-payment for certain prescription drugs. Thus, MPDIMA could force dual-eligible seniors to face larger co-payments than they do under current state Medicaid programs.

Dual eligibles experience high rates of chronic disease and have limited financial options. Therefore, dual eligibles may base their decisions regarding medication use on their ability to make the requisite co-payment rather than medical necessity of a given prescription. Under MPDIMA, such patient non-compliance is likely to increase. In order to address this troubling phenomenon, Congress should amend the statutory language to either reduce or eliminate the co-payment required of dual eligibles.

C. The Drug Formulary Requirements Under Part D and Medicare Advantage

Each drug plan approved by the Department of Health and Human Services (HHS) must have a drug formulary, which defines the specific extent of drug coverage provided to enrollees. A committee comprised of at least one pharmacist and physician must develop and review the formulary. Specifically, both MA and PDP plans require a formulary development process whereby the Pharmacy and Therapeutics Committee (PTC), using scientific evidence, determines the appropriate extent of coverage. MPDIMA mandates that an insurer’s drug formulary provide at

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80. ISSUES FOR DUAL ELIGIBLES, supra note 60.
81. MPDIMA, supra note 18, § 1395w-11. The “lowest income dual eligible” co-payment is either $1 for a multiple source drug or $3 for any other drug. Id.
82. GEN. ACCOUNTING OFFICE, supra note 60, at 51-53.
83. ISSUES FOR DUAL ELIGIBLES, supra note 60.
85. ISSUES FOR DUAL ELIGIBLES, supra note 60.
86. MPDIMA, supra note 18, 1395w-114.
87. Id. § 1395w-104.
88. Id. (requiring that the membership of the “Pharmacy and Therapeutic Committee” include “at least one practicing physician and one practicing pharmacist” and that both must possess expertise in elder or disabled care and be free of any conflict of interest with respect to the plan operator). Id.
89. Id. In developing and reviewing the formulary, the committee shall “base clinical
least two drugs for each therapeutic class. Furthermore, the statute requires plan sponsors to inform enrollees about the composition of the drug formulary. Unfortunately, these minimal requirements create the significant possibility that seniors may find their preferred drugs outside the scope of plans available to them within their geographical area.

D. Development of Therapeutic Classes

The statute charges United States Pharmacopeia (USP) to develop its own model categories and therapeutic classes to guide plan operators and their respective PTCs. However, the legislation does not require plans to follow USP guidelines and thus, significant incentives exist for companies to deviate from model classifications, potentially limiting drug options for seniors.

 Critics argue that allowing any deviation from USP model guidelines may create a considerable hardship for seniors, especially for those who require a particular brand of medication. In contrast, supporters of the bill would likely assert that the competitive market MPDIMA should result in significant drug offerings. Yet, should the market succeed in offering most seniors the drugs they need, market mechanisms may prove inadequate under MPDIMA by failing to provide appropriate pharmaceutical coverage for certain rare medical conditions. Additionally, plan operators may choose to disenfranchise these patients by creating only the most cursory form of therapeutic classes. This will limit seniors’ access to medically-

90. *Id.* (using the plural “drugs,” which include drugs within each therapeutic category, implies a requirement of two drugs per class).
92. ISSUES FOR DUAL ELIGIBLES, *supra* note 60.
93. MPDIMA, *supra* note 18, § 1395w-104.
94. THE HENRY J. KAISER FAMILY FOUND., PRESCRIPTION DRUG COVERAGE FOR MEDICARE BENEFICIARIES: A SUMMARY OF THE MEDICARE PRESCRIPTION DRUG IMPROVEMENT AND MODERNIZATION ACT OF 2003, available at www.kff.org/medicare/6112.cfm (Dec. 10, 2003) (explaining that plans may have incentive to deviate; however, those which follow the model guidelines set forth by the United States Pharmacopeia are deemed anti-discriminatory as a matter of law).
96. ISSUES FOR DUAL ELIGIBLES, *supra* note 60.
97. PARK & GREENSTEIN, *supra* note 95 (explaining that HHS is charged with oversight of formulary creation; such oversight could fail to remedy this problem of evasive therapeutic class creation).
necessary treatment.

E. Changes to the Formulary

The legislation permits plan operators to remove or replace any drug from the formulary at any time throughout the enrollment period\(^9\) by merely providing notice of such a change on an Internet website.\(^9\) Notably, although plan operators may modify the terms of the formulary at any time, enrollees may not change plans until the end of the calendar year during the prescribed open enrollment period.\(^10\)

To assure fairness, Congress should require every participating plan operator to offer at least one plan that meets the USP guidelines in each geographic market in which they operate. This would virtually guarantee seniors access to all medically-necessary treatment options. Furthermore, MPDIMA should prevent one-sided formulary modification by either disallowing the deletion of drugs from the formulary during the enrollment year, or by permitting enrollees to change plans following a mid-year formulary modification. In doing so, Congress would place enrollees and plan operators in a more equitable bargaining position and truly create the market type conditions that the drafters of MPDIMA purported to establish.

F. The Overall Systemic Bias in Favor of Managed Care

The aforementioned factors demonstrate an embedded statutory bias in favor of managed care. As previously mentioned, all Medicare Part D enrollees seeking prescription drug coverage could face difficulties with the coverage gap and limited drug formulary options.\(^10\) Since MA plan operators receive significant systemic advantages under this legislation—including the $1.3 billion subsidy, greater plan flexibility, and higher rates of per enrollee reimbursement—the integrated MA program will likely offer benefits not available to Part D PDP enrollees.\(^10\) Some of these benefits

\(^{98}\) MPDIMA, supra note 18, § 1395w-104 (stating that plan sponsors may remove drugs subject to the limitations upon minimum number of drugs per therapeutic class).

\(^{99}\) Id. (explaining that Internet access and usage by the elderly is quite low as compared to other age groups, according to a 2001 government survey which found that 63.9\% of those twenty-five to forty-nine years of age had Internet access while only 37.1\% over the age of fifty had such access). U.S. DEP’T. OF COMMERCE, NAT’L TELECOMMUNICS AND INFO. ADMIN., A NATION ONLINE: HOW AMERICANS ARE EXPANDING THEIR USE OF THE INTERNET, available at http://www.ntia.doc.gov/ntiahome/dn/anationonline2.htm (Feb. 2002).

\(^{100}\) MPDIMA, supra note 18, § 1395w-101. The statute does not permit mid-year enrollment unless the change of formulary altered the actuarial equivalence of the given drug plan.

\(^{101}\) PARK ET AL., supra note 22.

\(^{102}\) MA FACT SHEET, supra note 52.
may include a reduction in the coverage gap, lower premiums and co-payments, as well as programmatic benefits such as dental or vision coverage.\textsuperscript{103} Part D PDP enrollees will likely face sharp increases in monthly premiums that are far greater than the anticipated rate of inflation.\textsuperscript{104} In fact, one estimate projects the Part D monthly premium to rise from $35 per month to $58 by 2013.\textsuperscript{105} As enrollees face rising costs, many of the healthiest seniors may either forego Part D PDP enrollment altogether or join an MA plan that offers a minimal enrollment premium in exchange for diminished services.\textsuperscript{106} Either outcome would cause a downward spiral of the program by skewing the distribution of those who remain. As a result of this adverse selection problem, Part D enrollees may face even higher premiums and co-payments than was originally foreseen, as well as the potential withdrawal of plan operators from the Part D market.\textsuperscript{107}

Over time, a downward spiral of Part D may leave many seniors with only one viable option for drug coverage: the MA managed care program. Therefore, many seniors may never truly experience the choice of care that MPDIMA was created to provide.\textsuperscript{108} Rather, MPDIMA may result in a clandestine movement toward eliminating choice in Medicare through a systematic stacking of incentives in favor of Medicare privatization.\textsuperscript{109} Therefore, this legislation contains a clear bias in favor of managed care despite the fact that a large number of seniors do not wish to leave traditional Medicare.\textsuperscript{110} Congress should reconsider MPDIMA and revise its incentive structure to provide seniors with the possibility of exercising a genuine choice between enrollment in Part D and Medicare Advantage (MA).

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\textsuperscript{103} Id. Reduction of nominal co-payments, for example, may prove particularly attractive to the dual-eligible population.
\textsuperscript{104} Joint Econ. Comm. Rep., supra note 42 (describing that the increase in premiums is the result of the anticipated rise in medical expenses faced by the Medicare system).
\textsuperscript{105} Id.
\textsuperscript{106} Some MA plans may choose to provide minimal coverage at a lower cost to enrollees. Healthier Medicare beneficiaries will enroll into these plans leaving only the sickest seniors in the Part D plans.
\textsuperscript{107} See generally Berenson, supra note 36 (noting that such a downward spiral of plan withdrawal is not without precedent. In fact, as a result of adverse selection as well as other factors, many Part C Plus-Choice plans’ operators have faced significant difficulties and thus have withdrawn from a number of geographic markets).
\textsuperscript{108} President Signs Medicare Act, supra note 37.
\textsuperscript{109} Lieberman, supra note 22.
\textsuperscript{110} Reactions to the New Medicare Law, supra note 65.
\end{flushright}
IV. MPDIMA'S COST CONTAINMENT PROVISION

In addition to modifications of the programmatic offerings, MPDIMA also reforms other administrative and structural aspects of the Medicare system. Specifically, MPDIMA imposes a cost containment measure on Medicare’s budget. The cost containment provision requires the trustees of the Medicare program to both determine the amount of general revenue funding spent during the current fiscal year and project the amount of general revenue spending that will occur in the succeeding two fiscal years. If general revenue spending exceeds forty-five percent of Medicare’s total expenditures, then the statute requires the trustees to declare a Medicare funding warning.

The invocation of the cost containment warning is primarily linked to spending in Part B. As noted earlier, Part B is the portion of Medicare financed by general tax revenue which principally indemnifies enrollees’ outpatient and preventive care expenses. In contrast, Part A derives revenue from the payroll tax-financed Medicare trust fund and covers inpatient care spending. Yet, many recent efficiency gains in modern outpatient health care have resulted in a reduction of inpatient hospitalization, which has shifted expenditures covered by Part A to those encompassed by Part B. However, despite the trend towards greater utilization of outpatient services and the associated cost savings, the MPDIMA cost-containment provision penalizes Medicare for gains in the system’s efficiency. In other words, under the current cost containment provision, the more efficient modern medicine becomes, the closer

111. MPDIMA, supra note 18, § 1395i.
112. 42 U.S.C.A. § 801 (West 2004); MPDIMA, supra note 18, § 1395i.
113. MPDIMA, supra note 18, § 1395i(b)(4).
114. MPDIMA, supra note 18, § 1395i (stating that the trustees of the Medicare system declare “Excess General Revenue Medicare Funding” when general revenue Medicare outlays exceed 45% of total Medicare expenditures).
115. Id.
116. Id.
117. MPDIMA, supra note 18, § 1395k(a).
118. MPDIMA, supra note 18, § 1395d(-a)(1).
120. Id.
An Rx for the Modification of MPDIMA

Medicare moves towards a funding warning. The funding warning under MPDIMA carries significant consequences for the financial solvency of Medicare. The warning grants Congress and the President authority to create legislation that eliminates excess general revenue spending. This authority may become a catalyst for the Medicare program to raise premiums and cut the benefits available to Medicare recipients under the auspices of a system-wide cost overrun.

Due to the shift in favor of Part B outpatient spending, the forty-five percent cap appears to be a questionable metric for determining the need for Medicare cost containment. As other federal spending is not subject to similar caps, this arbitrary cap on spending is unprecedented. Taken together, MPDIMA’s inherent bias towards more expensive managed care and its misguided cost-containment strategy may threaten the financial solvency of Medicare. Therefore, Congress should eliminate financial caps in MPDIMA and instead create alternative mechanisms appropriately designed to contain Medicare program costs. Specifically, Congress should consider permitting the creation of a price negotiating authority or allowing safe drug re-importation, in addition to modifying the health savings accounts provision contained in MPDIMA.

V. ALTERNATIVE COST CONTAINMENT STRATEGIES

A. Best Price Negotiation

Congress should adopt recent proposed legislation that would permit best price negotiation. “Best price” negotiating allows governmental purchasers to achieve substantial reductions from full retail prices by arranging discounts with the leverage of their purchasing power. MPDIMA explicitly precludes Medicare officials from undertaking such a cost-saving device. Yet, the use of this mechanism is quite common in other federal agencies and health care programs. For example, the

121. 42 U.S.C.A. § 1105 (West 2004) (collectively, these provisions create a strict timeline for passage of legislation. Furthermore, floor debate and other procedural aspects of bill consideration are also limited).

122. PARK ET AL., supra note 22.


125. MPDIMA, supra note 18, § 1395w-102.

Medicaid program, the Veterans Affairs Department, and other federal government entities save substantial amounts of money each year through best price-type negotiation practices. Medicare administrators would potentially reap savings for both enrollees and taxpayers if Congress provided the administrators with complete authority to negotiate prices by using bulk purchasing power.

B. Safe Drug Re-Importation

Safely managed drug re-importation has the potential to reduce both governmental and consumer prescription drug expenditures. Therefore, in the absence of the ability to negotiate for the best price, Congress should explicitly permit the safe re-importation of drugs. The current statutory language contained in MPDIMA requires a safety certification by the Secretary of Health and Human Services (HHS). Yet, the Secretary has, to date, failed to allow any drug re-importation pursuant to his authority under MPDIMA. Several bills have been introduced that would allow safe drug re-importation to commence without the permission of the HHS Secretary. Congress should wait no longer for the Secretary’s certification and instead pass legislation that would create a mechanism for the safe re-importation of prescription drugs, as it has the potential to lower drug prices for Medicare beneficiaries.

C. Modifying Health Savings Accounts

A number of MPDIMA’s provisions do not directly address the drug benefit provision. One such provision is the creation of a tax-favored account called a Health Savings Account (HSA). HSAs allow non-

127. Id.
129. Id. This section is only slated to become effective if the Secretary certifies that re-importation would both “pose no additional risk to the public’s health and safety” and would result in significant cost savings on the covered products. Id.
elderly working individuals with high deductible health insurance policies to make tax-deductible deposits into a specially-segregated HSA and withdraw those funds for the payment of qualified medical services.\textsuperscript{133} The HSA provides a "front-end" tax advantage\textsuperscript{134} similar to other provisions of the tax code.\textsuperscript{133} However, an HSA differs from other types of savings accounts by providing an additional "back-end" tax advantage.\textsuperscript{136}

Despite their innocuous appearance, HSAs create several potential policy difficulties. First, the unprecedented front- and back-end tax savings in HSAs create a significant threat to the stability of the federal budget.\textsuperscript{137} This favorable tax treatment may prevent enormous sums of money from ever being subject to federal taxation and such loss of revenue must be offset through either spending cuts or other forms of revenue generation. The dual front- and back-end tax savings of these accounts is unnecessary. Rather, the simple provision of a front-end tax deduction creates a sufficient incentive for an individual to fund his HSA account.

Beyond the specific loss of revenue associated with these accounts, HSAs threaten a fundamental concept of the tax code.\textsuperscript{138} The precedent set by this legislation creates pressure to provide more favorable tax treatment to other savings accounts,\textsuperscript{139} such as those sanctioned by Section 401(k) of the Internal Revenue Code\textsuperscript{140} and other tax-deferred saving accounts such as Individual Retirement Accounts (IRAs).\textsuperscript{141} In fact, some lobbyists have already begun promoting the idea of allowing retirees to convert portions of their tax-deferred savings accounts into Retirement Medical Benefit Accounts (RMBAs).\textsuperscript{142} However, budget forecasters anticipate an influx of

\begin{itemize}
\item \textsuperscript{133} Id.
\item \textsuperscript{134} Id. § 223 (a).
\item \textsuperscript{135} 26 U.S.C. § 408 (2000); 26 U.S.C. § 401(k) (2000) (regulating IRA and 401(k) accounts that feature front end tax savings, whereby individuals can contribute their income and thereby avoid taxation both before and during the time in which their money remains in the segregated account).
\item \textsuperscript{136} 26 U.S.C.A. § 223(f)(1) (regulating recipients receipt of a back-end tax advantage as they incur no taxation when funds are withdrawn from the HSA account and used for qualified medical expenses).
\item \textsuperscript{137} See Robert Greenstein & Edwin Park, CTR. FOR BUDGET AND POL’Y PRIORITIES, HEALTH SAVINGS ACCOUNTS IN FINAL MEDICARE CONFERENCE AGREEMENT POSE THREATS BOTH TO LONG TERM FISCAL POL’Y AND TO THE EMPLOYER BASED HEALTH INS. SYS., available at http://www.cbpp.org/10-27-03health.htm (Dec. 1, 2003).
\item \textsuperscript{138} Id.
\item \textsuperscript{139} EDWIN PARK & ROBERT GREENSTEIN, CTR. FOR BUDGET AND POL’Y PRIORITIES, NEW RETIREMENT MEDICAL ACCOUNT PROPOSAL WOULD CREATE LUCRATIVE TAX SHELTER AND SWELL DEFFITS, BUT DO LITTLE TO HELP LOW AND MODERATE INCOME SENIORS WITH HEALTH CARE COSTS, available at http://www.cbpp.org/4-1904health.htm (July 22, 2004).
\item \textsuperscript{140} 26 U.S.C. § 401(k).
\item \textsuperscript{141} 26 U.S.C. § 408 (2000).
\item \textsuperscript{142} Id. (proposal would allow tax-free withdraw of the converted funds in a manner
massive tax revenues as millions of the current adult generation retire and draw upon their tax-deferred 401(k) and IRAs. This revenue could be lost if RMBA conversions were allowed. Thus, the HSA legislation should be amended to eliminate the provisions that would place a substantial strain on the Medicare and Social Security programs as well as the overall federal budget.

HSAs also may undermine the affordability of comprehensive employer provided health insurance if enrollees must use HSAs in conjunction with high deductible health insurance plans. The healthiest or most affluent workers may opt into these plans. If those workers were removed from the available low deductible insurance pool, insurers would have difficulty affordably grouping the remaining risk. Thus, this legislation may increase the premiums for those not enrolled in a high deductible insurance plan.

Congress should modify the HSA provision as contained in MPDIMA by removing the favorable treatment of back-end tax provided to HSAs. Additionally, Congress should eliminate the required link between HSAs and high deductible insurance, thereby allowing all insured persons to use such accounts regardless of the size of their particular deductible.

VI. AN RX FOR THE REFORM OF MPDIMA

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 represents the most significant overhaul of the Medicare system since its creation. For many individuals, the legislation represents progress towards providing America’s seniors with an optimal degree of outpatient prescription drug coverage. Yet, the legislation is far from efficient. Currently, MPDIMA has an aggregate projected cost of approximately $534 billion for the decade between 2004 and 2014. Reform of MPDIMA, as outlined herein, should create a more expansive, less expensive program than that which currently exists. Therefore, Congress should consider the aforementioned modifications of MPDIMA so as to create a more favorable prescription drug benefit.

First, to curtail programmatic costs, Congress should abandon MPDIMA’s so-called cost containment device and instead employ real cost control measures such as best price negotiation, safe drug re-importation,
and removal of the back-end tax advantage currently provided to Health Savings Accounts (HSAs). Using these cost reductions, Congress should modify MPDIMA’s treatment of dual eligibles by reducing or eliminating their required co-payment. Additionally, Congress should redefine “out-of-pocket cost” to allow employer spending to effectively compliment MPDIMA, thus potentially sparing many retirees from exposure to the standard coverage donut hole. To improve the quality of care provided by Medicare, new legislation should require plan operators to offer at least one plan in each geographic area, which strictly comports with the model guidelines crafted by United States Pharmacopoeia (USP). These requirements would ensure that each and every senior receives a baseline form of coverage as well as a more genuine choice between the newly constituted fee for service Medicare and managed care plans operated through Medicare Advantage. Furthermore, savings from cost-containment strategies such as best price negotiation or safe drug re-importation and revisions to the aforementioned HSA provisions can help fund these efforts.

A prescription drug benefit for seniors has been long overdue. However, MPDIMA increases costs and forces seniors into an inefficient and restrictive managed care system with the potential to threaten the solvency of Medicare. Accordingly, Congress should modify the MPDIMA legislation so that seniors receive less expensive, but more expansive coverage while taxpayers enjoy a more efficient system.