A History of Creating the Medicare Prescription Drug Benefit / Striking Compromises, Avoiding Past Mistakes, and Minding Budgetary Constraints

Prepared by:
Jonathan Blum
Avalere Health LLC

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When the Medicare Modernization Act of 2003 (MMA) was signed into law on December 8, 2003, many of those involved in the development of the legislation remarked it was the most technically complicated and intricate piece of legislation they could remember ever working on. The MMA is nearly 1,000 pages long and introduced new terminology that has now become commonplace among politicians, health policy analysts, and Medicare beneficiaries. These terms include donut holes, PDPs, risk corridors, and low-income subsidies. Its technical complexity was the result of several confounding forces including: 1) delicate compromises that barely held together upon final passage of the legislation; 2) historical lessons from previously enacted prescription drug legislation; and 3) the Congressional budget process. While the new Medicare drug benefit has many critics, the criticisms often dissipate when the forces that shaped it are completely understood.

Delicate Compromises

Benefit Design

When the Medicare prescription drug benefit was debated in Congress there was almost uniform agreement that Medicare should be expanded to cover prescription drugs. However, there was little agreement on many important components of the legislation, including the generosity of the benefit, the treatment of beneficiaries who have both Medicare and Medicaid coverage (i.e., “dual eligibles”), and the role of private insurance plans.

Most agreed that the benefit should be designed to serve all Medicare beneficiaries, while providing additional assistance to those most in need, specifically low-income beneficiaries and those who incur very high prescription drug expenses. As a result, the Medicare prescription drug benefit was designed to provide Medicare beneficiaries immediate assistance through reduced
drug costs, both from expanded insurance coverage and from being able to access negotiated
drug prices when the beneficiary is responsible for the cost of the drug (i.e., during the initial
deductible period and the coverage gap, or “donut hole”).

The benefit was further designed to provide protection against catastrophic drug costs for all
participating beneficiaries. Implicitly, Congress sought to promise constituents that the benefit
would not be capped—even for individuals with extraordinarily high drug costs. Furthermore,
Congress wanted to ensure that beneficiary cost sharing is limited for those with very high drug
costs. Ultimately, Congress structured the benefit to dramatically reduce cost sharing for individu-
als whose out-of-pocket costs exceed $3,600 per year, which under the standard benefit struc-
ture, translates to $5,100 in total drug costs for the 2006 benefit year. Less science, more art, the
justification for setting the catastrophic threshold did not have a clinical basis, but was set at a
level at which it was estimated that about 5 percent of beneficiaries would incur drug costs be-
yond the threshold and many members of Congress believed this was a reasonable amount.
Some members of Congress expressed a desire for beneficiaries to have no additional expenses
after the catastrophic threshold is reached. However, others expressed concerns that beneficiar-
ies should be required to pay some amount above the threshold to control federal costs by limiting
unnecessary consumption of drugs. As a result, beneficiaries are required to pay 5 percent of the
cost of the drug even after the catastrophic threshold is reached.

**Dual Eligibles**
The decision to shift all dual-eligible beneficiaries into the new Medicare drug benefit was by far
one of the most contentious decisions during the 2003 legislative debate. The Senate-passed bill
did not include this shift—dual eligible beneficiaries would have continued to receive prescription
drug coverage from state Medicaid programs. Since dual-eligibles already received generous
prescription drug coverage, the Senate decided that available resources should be targeted
toward those without drug coverage, although many members of the Senate opposed this policy.
The Bush Administration strongly supported dual eligibles remaining in state Medicaid programs
for their drug coverage. It felt that such a shift would be an inappropriate windfall to states.
Some observers also speculated that the Bush Administration wanted to delay consideration of
dual eligibles’ drug benefits to a later date when broader Medicaid reform would be considered.
Keeping the duals in state Medicaid programs would maintain financial pressure on states,
bringing the governors to the negotiating table on Medicaid reform.

Most beneficiary advocates argued that the Senate policy violated a long-held principle of the
Medicare program—all beneficiaries, irrespective of income, are treated first and foremost as
Medicare beneficiaries. Leaving the dual eligibles in state Medicaid programs would create a two-
tier standard, violating the social insurance nature of the Medicare program. The pharmaceutical
industry also largely supported shifting the dual eligibles into the new Medicare program. 2003
was a time of tremendous change in state pharmacy benefits. States were rapidly implementing
cost-containment measures to restrict access to drugs through quantity limits, higher co-pays, and
preferred drug lists. The pharmaceutical industry, as well as many beneficiary advocates, believed

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1 As explained in a later section of the paper, Congress defined out-of-pocket expenses as only those incurred by the beneficiary, a family
member, or a qualified state pharmaceutical assistance plan (SPAP). Other contributions do not count towards the out-of-pocket limit.
Beneficiaries who receive additional assistance with their out-of-pocket expenses may have higher annual drug costs than $5,100 before the
catastrophic protection kicks-in.
that the Medicare program would provide superior access than state Medicaid programs, despite the fact that Part D plans would be permitted to implement restrictive formularies.

In the end, Congress decided to shift dual eligibles into the new Medicare drug benefit, but not without making some difficult tradeoffs. As discussed in a later section of this paper, states are required to continue to fund a majority of their current costs associated with dual eligibles’ drug benefits. And dual eligibles are subject to the same formulary and other private plan benefit designs as all other Medicare beneficiaries.

**Low-Income Subsidies**

Virtually all members of Congress hailed the additional assistance the drug benefit provides to low-income beneficiaries. For beneficiaries below 135 percent of poverty (annual incomes below $12,920 for individuals and $17,321 for couples in 2006), the benefit provides comprehensive drug coverage, with low cost-sharing and no premium requirements. For beneficiaries below 150 percent of poverty (annual incomes below $14,355 for individuals and $19,245 for couples in 2006), the benefit provides almost equally generous coverage, with gradually higher cost-sharing requirements and reduced premiums. The Senate bill provided additional assistance for those up to 160 percent of poverty, while the House bill provided additional assistance to those only up to 135 percent of poverty. A natural compromise point was somewhere in the middle: 150 percent.

However, conservative Congressional members expressed concerns about the generosity of the low-income benefit. They were concerned that seniors with significant assets would inappropriately receive assistance and that minimal cost-sharing would inappropriately increase consumption. To address these concerns, the legislation includes an assets test, whereby beneficiaries have to attest they have minimal liquid assets in addition to meeting the income requirements. Although supporters of the bill may have been overly optimistic about the number of beneficiaries that would qualify for the more generous coverage, the imposition of the assets test likely reduced the number. Current estimates indicate that nearly six million beneficiaries are eligible for this assistance. The legislation also includes a requirement that all low-income beneficiaries are subject to minimal copayments that vary with income, which will be increased annually to ensure that beneficiaries have incentives to limit prescription drug consumption. The legislation discourages state contributions to “buy-down” or subsidize dual eligibles’ copayments by precluding federal matching funds for such costs under Medicaid. As a result, many low-income advocates expressed fear that dual-eligible beneficiaries may incur higher cost-sharing responsibilities than they did under their Medicaid-provided benefits.

**Private Health Plans**

The new prescription drug benefit fundamentally changes the nature of the Medicare program. It is administered by private health plans and most beneficiaries have to affirmatively enroll in a private health plan to receive benefits from the program.

This new structure was driven by the almost uniform desire among members of Congress to have private entities administer the benefit and a political decision to not require Medicare beneficiaries to enroll in a health maintenance organization (HMO) or other comprehensive private health plan to receive the new benefit.
Virtually every piece of legislation introduced in Congress during the past five years to add a prescription drug benefit would have the benefit administered by private entities, either by pharmacy benefit managers (PBMs) or private health plans. The general feeling behind these proposals is that private organizations will be able to deliver benefits more efficiently because they have a freer hand to impose cost-control measures, such as formularies, prior authorization, and step therapy, and to implement programs to switch beneficiaries to lower-cost drugs, such as generics. Unlike private insurers, which typically contract with one PBM or administer their own drug benefits, most members of Congress believed that beneficiaries should be offered a choice of drug plans to ensure that they could find a plan that offers coverage appropriate for their particular drug needs.

The decision to offer stand-alone drug plans was a result of the politics of Medicare—most members of Congress were hesitant to suggest that a beneficiary should be required to leave the traditional fee-for-service program to receive the new drug benefit, even as these same members strongly supported private sector administration of the new benefit. The Bush Administration originally proposed in 2003 that a comprehensive drug benefit would be offered only to those Medicare beneficiaries who enroll in a Medicare HMO or a newly created regional PPO plan. Medicare has had a long history with managed care plans. About 12 percent of Medicare beneficiaries were enrolled in a Medicare HMO in 2003. But the program has had a troubled history. Over the past couple of years many plans exited the program as Congress reduced payment rates in the late 1990s. Moreover, despite generous payment rates, Medicare HMOs were hesitant to offer services in rural areas of the country, largely due to difficulties recruiting hospitals and physicians to participate in their networks. The Bush Administration, sensitive to the past history of the program, proposed regional PPOs that they believed would prove more attractive to Medicare beneficiaries than HMOs, since most people in the country receive their health benefits from a PPO. It also argued that a regional PPO would provide access in rural areas, since they would be required to offer services in rural areas as a condition to offering services in urban areas.

The Administration’s proposal to require Medicare beneficiaries to enroll in a private HMO or PPO to receive the promised drug benefit was not well received. An alternative would be for the program to contract with stand-alone drug insurance plans that would offer the drug benefit to fee-for-service enrollees. Supporters of such a model argued that stand-alone drug insurance plans would have stronger financial incentives than the government or a PBM operating under a fee-based contract to reduce drug costs through aggressive negotiations with drug manufacturers and by aggressively switching beneficiaries to lower-cost drugs. The Congressional Budget Office (CBO) reinforced this view by estimating that private plans, if required to bear insurance risk, would negotiate lower prices than if only required to put their management fees at risk. CBO also estimated that private risk-bearing plans would negotiate lower prices than if the federal government directly administered the benefit. However, many argued that there was no such thing as a stand-alone drug insurance plan and questioned whether any entity would be willing to offer insurance for only drugs. It was analogous to offering insurance for a haircut, in the words of the president of the former Health Insurance Association of America (HIAA).

In the end, Congress devised a compromise. The current Medicare HMO program was strengthened through enhanced federal payments, especially targeted to those parts of the country hardest hit by previous payment cuts. Congress also authorized the creation of regional PPOs, and established even greater subsidies to foster their development. Both HMOs and PPOs would be
required to offer the new drug benefit to their members. Moreover, Congress authorized the Centers for Medicare and Medicaid Services (CMS) to contract with stand-alone drug plans (PDPs) that would offer the drug benefit to those beneficiaries who remain enrolled in the traditional fee-for-service program. All plans would be required to submit bids to CMS and their premiums for the drug benefit would be determined based on the average of plan bids. Congress felt that this bidding system would provide strong economic incentives for plans to keep costs down and bid low to attract beneficiaries.

To address criticisms that PDPs would never materialize, the legislation included a complicated system of subsidies to PDPs, including federal reinsurance payments to PDPs for beneficiaries who reach high out-of-pocket expense levels. The legislation also included risk-corridor payments which allow PDP sponsors to share market risks with the Medicare program, to encourage market development and to balance the tension between market efficiency and government stability. Congress believed a market would develop if plans were required to bear only minimal risk during the initial years of the benefit, reasoning that over time, plans would be willing to bear more risk. Congress also authorized CMS to contract with non-risk based PBMs to serve as a “fallback” in any part of the country that did not attract at least two private plans.

**Remembering the Past: The Legacy of the Medicare Catastrophic Coverage Act**

Many of the provisions in the Medicare prescription drug benefit stemmed from the lessons learned from the repeal of the Medicare Catastrophic Coverage Act (MCCA) in 1989. The images of the fallout from its repeal weighed heavy on the minds of members of Congress and they vowed to not repeat the mistakes from the past. In 1988, Congress enacted the MCCA, which greatly expanded the Medicare program. It was designed to address many of the program’s benefit gaps to ensure that the elderly were not impoverished by catastrophic illness. Among other changes, the MCCA included a universal prescription drug benefit, which was much more modest than the benefit enacted in 2003. It offered a $600 deductible in 1991, and required 50 percent cost-sharing in 1991, 40 percent in 1992, and 20 percent in 1993 and thereafter. The costs of the expanded benefits were borne by Medicare beneficiaries, through increases in the Part B premium and an income tax surcharge on higher-income beneficiaries. Many Medicare beneficiaries vehemently opposed the changes, especially the notion that seniors would have to pay for the changes themselves through higher premiums and taxes. Moreover, many seniors with generous retiree coverage believed that they would lose their coverage as a result of the Medicare expansion. Congress repealed the new benefit expansion before it went into effect due to largely to vehement opposition among seniors. Television images of senior citizens chasing former House Ways and Means Chairman Dan Rostenkowski into his car at a local senior center in Chicago loomed large on Congressional drafters in 2003.

Congress gleaned four significant lessons from the repeal of the MCCA. First, the new benefit would have to be voluntary; no one would be required to enroll if he/she did not want to. Second, the federal government would provide the majority of the funding for the new benefit expansion. Third, all beneficiaries should see more immediate benefit. And finally, the benefit would provide assistance to employers and union-sponsored plans to minimize any dropping of benefits.
Congress took great strides to ensure that the new Medicare prescription drug benefit is optional for all Medicare beneficiaries; supporters continue to stress the voluntary nature of the program.\(^2\) To reinforce the voluntary notion, Congress included provisions to require beneficiaries to make an affirmative choice to enroll in the program. Unlike Medicare Part B in which beneficiaries are automatically enrolled upon becoming eligible for Medicare Part A, most Medicare beneficiaries will have to apply to enroll; specifically, they must apply to a participating private plan. Congressional drafters were aware that such an opt-in mechanism may reduce overall enrollment—very few beneficiaries opt-out of Medicare Part B coverage. However, Congress sought to assure seniors that the new coverage, unlike MCCA, would be voluntary.

The new Medicare prescription drug benefit provides participants nearly a 75 percent premium subsidy, similar to Medicare Part B. Those who qualify for low-income assistance receive an even greater subsidy amount. Congress included such a subsidy amount to ensure broad participation, but also to counter the main criticism of the MCCA that beneficiaries would have to pay higher premiums for a drug benefit without receiving any benefit. Moreover, Congress sought to ensure that virtually all participants will receive immediate benefits upon enrollment. Unlike the MCCA, beneficiaries will face only a $250 deductible (less if they select a plan that offers more generous coverage) and 25 percent cost-sharing up to a $2,250 coverage limit. Lower deductible amounts were considered; however, fiscal conservatives countered that lower deductibles would lead to unnecessary increased consumption of prescription drugs.

Finally, Congress wanted to avoid any political fallout from seniors who believed that their generous retiree drug coverage would disappear upon implementation of a Medicare prescription drug benefit. Many employers had been reducing prescription drug coverage for current and future retirees. Some employers publicly stated that they would consider further reductions if Medicare began offering a prescription drug benefit. Nearly one-third of seniors had prescription drug coverage provided by a former employer or union plan in 2003. The fallout from employers dropping coverage loomed large, especially since the new Medicare drug benefit with its donut-hole benefit design was unlikely to match drug coverage provided by most employers. Congress was unwilling to consider requiring employers to maintain drug coverage and many believed such a requirement would have been deemed unconstitutional. Instead, Congress included more than $75 billion over 10 years in subsidies to for-profit and non-profit entities that maintained drug coverage for their Medicare-eligible retirees. The subsidies were made exempt from taxes, providing an even greater subsidy amount to for-profit entities. Some fiscal conservatives charged that the subsidies were a gross form of corporate welfare; however, Congressional drafters believed the subsidies were necessary to avoid large-scale dropping of retiree coverage. Moreover, the retiree subsidies were considered a form of cost-savings since the estimated amount of the retiree subsidy was far less than the costs of the federal subsidy for each enrollee in the new prescription drug benefit, according to CBO.

### Designing Around Budget Constraints

Many of the specific provisions of the Medicare prescription drug legislation were pre-determined by the 2003 Congressional budget debate in March-April 2003. The debate produced a joint resolution that allocated a net $400 billion in new federal spending for Medicare over fiscal years 2004-2013. Congressional resolutions do not have the force of law; they are non-binding policy

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\(^2\) Dual-eligible beneficiaries are auto-enrolled in the new benefit
statements. However, they serve as a framework for legislative action and place roadblocks in front of any member of Congress who proposes detractions from the agreed upon allocation.

Most significantly, the $400 billion allocation pre-determined a coverage gap, or donut-hole, in the benefit. It was virtually impossible to provide: 1) a uniform benefit to all Medicare beneficiaries, 2) catastrophic coverage to those with the highest drug costs; and 3) additional subsidies to provide assistance to low-income beneficiaries without a significant gap in coverage. A benefit that provided comprehensive coverage to all Medicare beneficiaries would have cost at least two times more over the 10-year period. Congress and virtually every stakeholder knew that the $400 billion budget allocation would necessitate a significant gap in the prescription drug benefit at the time of the earlier budget debate.

But even with the existence of a donut hole, Congress was hard pressed to design the prescription drug benefit within the limits of the $400 billion budget allocation. The increased payments to managed care plans and other health care providers were offset by payment reductions to some provider groups and increases in the Part B deductible and, for the first time ever, higher Part B premiums for high-income beneficiaries. Yet, Congressional drafters had to come up with creative ways to contain spending on the new prescription drug benefit to $400 billion over the 10-year period. One of the most creative savings measures was a redefinition of how beneficiary out-of-pocket costs would be treated under the new benefit. Under the benefit, catastrophic coverage kicks in after a beneficiary incurs $3,600 in out-of-pocket costs. But the legislation defines out-of-pocket costs as those paid for by the individual, a family member, or qualified state pharmaceutical assistance program (SPAP). Contributions provided by other entities, such as a former employer, would not count. Such a definition of true out-of-pocket costs (i.e., “TrOOP”) forces more beneficiaries to pay more of their drug costs out of their own pocket, effectively limiting the number of beneficiaries who receive catastrophic assistance. The definition also creates an unintended incentive for plans not to offer additional coverage in the donut hole since these contributions will not count towards beneficiaries’ out-of-pocket costs. Yet, the TrOOP definition provided additional resources to Congressional drafters to improve the benefit, such as the generous low-income subsidies.

Congress devised a couple of other creative budget measures to reduce overall costs. All prices for Part D drugs, whether paid for by a participating Medicare plan or by an employer which receives the Medicare subsidy, are exempt from the calculation of Medicaid best price. The intention of the provision was to provide incentives for manufactures to offer deeper discounts to drug plans and employers than they offered to state Medicaid programs. Many economists had pointed out that the Medicaid best price legislation created an artificial floor for drug prices. The Part D benefit would be exempt from this requirement.

Congressional drafters also devised a novel concept to require states to compensate the federal government for assuming the drug costs of dual-eligible beneficiaries. Under the legislation, states would be required to pay a fixed-monthly amount to the federal government for every dual-eligible beneficiary enrolled in the program. An ominous name was coined for this payment requirement: “clawback,” to denote the federal government grabbing its rightful share of money. Never in recent memory has the federal government required states to make such a payment, which some governors are planning to Constitutionally challenge in federal court. Although the clawback was designed to produce savings to states through a reduced payment requirement over time,
Congressional drafters generally knew that it would place short-term hardship on states at a time of extreme budget pressure. Yet, many state and beneficiary advocates acknowledged the need for clawback to offset the costs of dual-eligible beneficiaries being shifted into the new Medicare benefit, a strong policy principle to them as previously described.

Congress decided that the new Medicare drug benefit should be voluntary to blunt past criticisms associated with the MCCA; however, the voluntary nature of the program created unique cost pressures. While a voluntary program may reduce the number of beneficiaries who participate in the program, those who did decide to participate may have higher drug costs than the expected average beneficiary. Beneficiary premium contributions would be less than expected to offset the costs of higher-spending beneficiaries. In short, the voluntary nature of the program created a risk of adverse selection, which would increase overall costs. As a result, Congress included a narrow window of time by which beneficiaries may enroll in the new benefit. Despite concerns that beneficiaries may need some time to understand the new benefit and to select an appropriate plan, Congress included only a six-month window for current beneficiaries to decide to enroll. Beneficiaries enrolling after the six-month window will be required to pay increasingly higher premiums, or a premium penalty, for each month of delayed enrollment.

While there were many other details of the legislation that were driven by budget constraints, the decision to require the United States Pharmacopoeia (USP) to define model therapeutic drug classes merits particular mention. There was general consensus among most Congressional drafters that plans should be granted broad discretion to design their own formularies within some parameters and subject to CMS review to limit discrimination. The Senate version of the legislation had proposed to require CMS to establish a single definition of a therapeutic class to ensure that plans operated under the same rules. At the time of drafting, there was not one recognized therapeutic class definition. CBO determined that the creation of one standard definition would increase costs of the overall benefit since plans may be too restricted in their formulary development under one rigid definition, especially one crafted by an agency subject to pressure by manufacturers and patient advocates to require as many drugs as possible. Yet, Congressional drafters were concerned that without a common standard, plans may inappropriately restrict access to medications. A compromise was found. The legislation stipulates that HHS would be required to contract with the USP to develop model guidelines for a therapeutic class. Plans are not required to follow the guidelines, but those that do face an easier formulary review by CMS than those that do not. Had CBO not highlighted the cost-concern, the final legislation would have most likely included a requirement that plans follow one single therapeutic class definition in their formulary development.

The Next Chapter

The jury is still out on the success of the new prescription drug benefit. In some respects, the steps taken to ensure timely benefit implementation were more successful than Congressional drafters and supporters had expected. Despite predictions from prominent Medicare experts, CMS issued implementing regulations and guidance documents in time for plans to complete their bids on time. As a result, it reasserted itself as a stable business partner with health plans and other provider partners. And despite concerns that private stand-alone drug plans would not materialize, CMS was overwhelmed with interest among insurance companies and PBMs to offer the benefit. So far, it appears that Congress and CMS created an attractive market environment for
private health plan participation. Moreover, the premium support system Congress devised for the
drug plans in which the federal government contributes a defined amount toward Part D premiums
with beneficiaries paying remaining amount may in fact produce greater cost efficiencies. The
average plan bids for 2006 were lower than expected, resulting in much lower premiums for the
new prescription drug benefit.

However, there are a variety of issues that surfaced post-January 1, 2006 that may have slowed
the enrollment of remaining eligible beneficiaries into Part D plans. While the strong market
response may have created greater cost efficiencies, at least for 2006, consumer research to date
indicates that many seniors were perplexed by the wide array of plan choices and benefit designs
and formulary offerings. There is tremendous variation in the cost-sharing and formularies among
participating plans. Seniors may also see variation in the prices of drugs paid at the pharmacy
depending in which plan he/she enrolls.

Additionally, there were several significant Part D data issues that negatively affected low-income
Medicare beneficiaries. Low-income beneficiaries were denied prescriptions at the point of sale or
were overcharged for prescriptions for which they should have only been charged nominal co-
payments. In other instances, pharmacists were unable to locate beneficiary plan assignments.
Dual eligibles who switched into plans other than the ones into which there were auto-enrolled had
the most difficulties. These situations occurred regardless of safeguards put into place by CMS,
prompting many states to subsidize drugs costs for low-income beneficiaries until the kinks in the
system were smoothed out. CMS has worked hard to address data system errors and other
implementation issues, and most of them appear to have been abated.

Although Part D encountered many issues with implementation, some of the major mistakes of
the MCCA have been averted. Some major beneficiary groups, while advocating for the quick
remedy of identified systems errors, remain committed to the success of the benefit. And to date,
few stakeholders have called for its repeal. It is interesting to note that polling data collected to
date is very different from polling data collected after enactment of the MCCA. After the MCCA’s
enactment, pollsters found that seniors became more opposed to the MCCA after they learned
more about it. The opposite appears true today with available polling data date. Pollsters find
that seniors are more favorable toward the new Medicare drug benefit the more they learn about
it and understand its benefit design.

The new Medicare drug benefit will undoubtedly be modified over time to reflect changes in
market dynamics, beneficiaries’ preferences, and future budget pressures. Much research and
analysis will be necessary to inform future modifications. Does the new drug benefit reduce
beneficiaries’ out-of-pocket expenses? Does it improve clinical outcomes and reduce unneces-
sary hospitalizations and other expensive health care services? Do competitive pressures and
market dynamics reduce the cost of drugs and lead to more efficient prescribing practices? Are
Medicare beneficiaries able to navigate a complicated choice model?

While future research will be vital to improve the benefit, stakeholders should also be mindful of
the difficult tradeoffs that were made in 2003. The same pressures, especially the budget pres-
sures, are likely to be present in any future deliberation over the new Medicare prescription drug

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benefit. The complicated nature of the program was driven by creative solutions to balance many competing tensions. Legislative efforts to modify the new benefit should be mindful of the difficult and contentious negotiations that produced the Medicare drug benefit. In the end, Congress found a delicate balance to these tensions in 2003. Future modifications will have to balance the same tensions.