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Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA):

Prescription Drug Benefit Implementation in Virginia and Review of Pending State and Federal Legislation

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Signed into law by President George W. Bush on December 10, 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) provides the largest benefit expansion in Medicare's history.[1] The legislation enacted major substantive changes to the Medicare program that did not come without a high price tag. The prescription drug benefits alone are expected to cost just over $410 billion over 10 years.[2]

Introduction

This Issue Brief focuses on the prescription drug benefit provisions of the new law, in particular the temporary prescription drug discount card program, which began in the spring of 2004, and the practical implications of the discount drug card program on Virginians. A discussion of recent Virginia and pending federal legislation aimed at addressing perceived shortcomings of the MMA follows, including the issues of prescription drug importation and government-leveraged price negotiation with drug manufacturers, the coverage gap (or "doughnut hole") and its effect on low-income individuals, and various Medicare-quality and cost-control measures.

Prescription Drug Benefit

Perhaps the most significant and certainly the most talked about change to existing Medicare law is the addition of a prescription drug benefit. Administered by the Centers for Medicaid and Medicare Services (CMS), Medicare is the nation's largest health insurance program with more than 40 million beneficiaries nationally, including 947,000 in Virginia. It covers people age 65 and over, many disabled people under age 65, and people with end-stage renal disease (permanent kidney failure treated with dialysis or a transplant).[3] Of this total number of beneficiaries in Virginia, the CMS estimates that 187,000 of them do not have any prescription drug coverage.[4] The new prescription drug benefit program, Medicare Part D, is aimed primarily at helping these individuals by providing them with assistance in paying for the prescription drugs that they need, and beginning in 2006, all Medicare beneficiaries will be able to enroll in a prescription drug plan.[5]

Despite potential variations, in general the plans will entail the following:

- A premium of approximately $35 per month.
- A $250 deductible, paid by the consumer.
- Medicare then pays 75 percent of drug costs between $250 and $2,250.
- The consumer pays 100 percent of drug costs above $2,250, until out-of-pocket costs reach $3,600.[6]
- Catastrophic coverage: Medicare will then pay approximately 95 percent of the costs after the consumer has spent $3,600.[7]

In addition to these general provisions, the MMA includes targeted prescription

drug assistance for certain low-income beneficiaries. Many people with incomes up to 135 percent of the poverty level ($12,569 for individuals and $16,862 for married couples) will not be required to pay any premiums, and will only be subject to co-payments of $2 for generic drugs and $5 for brand name drugs. For individuals with incomes between 135 and 150 percent of the poverty level, these benefits start phasing out and a sliding-scale premium will be charged, co-payments increased, and a $50 deductible added. New income limits for determining eligibility for low-income assistance will be set in 2005.[8]

In addition to the income test, the MMA requires an asset test in order to determine eligibility for low-income prescription drug assistance. Beneficiaries living at or below 135 percent of the poverty level may have up to $6,000 in assets per individual or $9,000 per couple, while those falling between 135 and 150 percent of the poverty level are limited to $10,000 in assets individually or $20,000 per couple. Critics of the dual income/asset test point out that an estimated 1.8 million individuals who would otherwise be eligible for benefits based on income may be excluded from low-income prescription drug assistance for failure to meet the asset requirements.[9]

Prescription Drug Discount Card

Although the permanent prescription drug benefit provisions do not become effective until January 1, 2006, since May of 2004 Medicare beneficiaries have been able to enroll in the Medicare-Approved Discount Drug Card Program. Anyone eligible for Medicare Part A or Part B who is not already receiving Medicaid outpatient prescription drug coverage is eligible. There are no income qualifications; however, certain low-income beneficiaries may be eligible for the $600 annual credit (discussed below). States, pharmacies, retiree drug coverage, and various other programs will compete with the Medicare-approved cards by offering similar prescription drug discounts. These programs, however, offer alternatives to the Medicare-approved discount drug cards and are not subject to all of the same requirements and standards regarding discounts, coverage, and eligibility.

This program is voluntary for eligible applicants and is intended to bridge the gap until the MMA's drug benefit takes effect in 2006 by providing discounts for regular prescription drugs until that time. According to the CMS, the cards are expected to provide consumers with 10-15 percent average savings and as much as 25 percent or more on individual prescriptions. The CMS estimates that in 2004 alone, 7.3 million people will save a total of between $1.4 billion and $1.8 billion by enrolling in the program. During the course of this program, the CMS estimates that the drug card subsidies will total (or beneficiaries will save) more than $8 billion nationally, including $194 million in Virginia.[10]

Card sponsors can charge up to $30 per year for enrollment, and fees for cards available in Virginia range from no enrollment fee up to the $30 maximum, with the typical fee falling between $20 and $30. At least 36 sponsors provide Medicare-approved prescription drug cards in Virginia. In addition, Virginians have at least eight statewide, company-sponsored programs and seven regional and membership programs from which to choose. For a full listing of all prescription drug programs in Virginia, including both Medicare-approved cards and other alternatives, contact the Virginia Department for the Aging at 1-800-552-3402 or see the listing provided on the Department's website at http://www.aging.state.va.us.

As early as May 2004, eligible applicants could begin applying for a discount card (to become effective in

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June). Beneficiaries can apply for only one Medicare-approved card at a time (there are no limits on the number of non-Medicare-approved cards), and must remain with that card for the rest of the year. However, one may change cards under the following circumstances:

- Moving to another state where the current card is not offered;
- Entering or leaving a long-term care facility;
- Leaving or joining a Medicare managed care plan;
- Private company stops offering that particular discount card; or
- During the coordinated election period (November 15–December 31, 2004), pursuant to which the new card will become effective January 1, 2005.[11]

Beneficiaries can use their discount cards to purchase covered prescription drugs from pharmacies or mail order suppliers that participate in their card sponsor's network. All cards are required to offer at least one drug in each of the 209 categories that the CMS has identified as the most frequently used by Medicare beneficiaries, in addition to at least one generic drug in a minimum of 115 of those 209 categories.[12] However, all cards do not offer the same drugs, nor are they required to offer discounts on all drugs that they include in their formulary. In addition, a sponsor may without prior notice change which drugs it covers and the prices it charges for those drugs. Therefore it is important for individuals to review the lists of covered and discounted drugs when enrolling in drug card program to make sure it offers the best coverage and savings for the individual.

Information about card sponsors' formularies and prices, and changes to either, are required to be posted in each card sponsor's website and must be available through their call center. This information can also be obtained through 1-800-MEDICARE, or http://www.medicare.gov/, which is updated weekly and contains a useful and confidential guide to choosing a Medicare-approved discount drug card.

Transitional Assistance Program for Low-Income Individuals

As mentioned above, the MMA also provides a $600 credit per year in 2004 and 2005 on Medicare-approved discount cards for beneficiaries whose incomes are 135 percent, or below, the federal poverty level. Medicare will pay the discount drug card enrollment fee for these individuals. Meanwhile, when utilizing the $600 credit, those earning at or below 100 percent of the poverty level ($9,310 for individuals or $12,490 for couples) will pay five percent coinsurance, and those earning between 100 percent and 135 percent will pay 10 percent. Joint prescription drug card/$600 credit eligibility forms are available from http://www.medicare.gov, or on the selected card sponsor's website.

Individuals who qualify for the credit will pay the following portion for each prescription:

- Five percent of the discounted price for each prescription until the credit is used up if one's monthly income is between $0 and $776 (single) or between $0 and $1,041 (married).
- Ten percent of the discounted price for each prescription until the credit is used up if one's monthly income is between $777 and $1,048 (single) or between $1,042 and $1,406 (married).

Once the $600 credit is used up, eligible beneficiaries will then pay the full discounted price for each prescription offered through the Medicare-approved drug discount card program in which they are enrolled.[13]

The CMS estimates that seven million Medicare beneficiaries, including 162,000 in Virginia, are eligible for this program. The CMS expects about 4.5 million beneficiaries to participate, saving more than $5 billion nationally, while 105,000 participants in Virginia will save approximately $126 million over the two-year duration of the program.[14] On an individual basis, the CMS estimates average annual drug costs for this

population at $1,400, so a $600 credit will equal a 43 percent savings, on average.

Issues Addressed By Recent State and Federal Legislation

Numerous bills have surfaced in Congress and the General Assembly during the past six months that address or seek to modify the MMA as signed into law in December 2003. The proposed bills target the perceived problem areas such as the "doughnut hole," the prohibition on negotiation and importation, and the overall quality and cost of the program. In addition, due to concern over the complexity of the MMA and the discount drug card program, the General Assembly took steps this year to disseminate information and educate the public.

Although a large number of legislators are attempting to "fix" the MMA, many think that the bill will be an important part of President Bush's re-election strategy, and as such, any attempt to target the legislation is unlikely to pass.
Moreover, since the bulk of the new Medicare law does not fully take effect until 2006, there may also be substantial resistance to any changes prior to that time.

Despite such considerations, many bills have been introduced and gained both bi-partisan and public support. Senator Kent Conrad (D-North Dakota) introduced a comprehensive bill (Senate Bill 2343) that touched on each of the controversial provisions of the MMA, which the Senator refers to as a "good first step."[15] However, the majority of the proposed legislation has been on much smaller scale, thus the following bills are summarized and categorized by the specific issues they target.

Importation of Prescription Drugs and Price Negotiation

The most frequently proposed bills this year have called for the repeal of the provision prohibiting the Secretary of Health and Human Services from negotiating lower prices for prescription drugs. House Bills 3672 and 3671 and Senate Bill 1999 all provide for the Secretary to enter into negotiations with drug companies to lower prices for America's seniors.

On July 13, 2004, the House of Representatives approved a measure by a 389-31 margin that would allow Americans to buy prescription drugs from Canada and other countries. At the urging of Representative Marcy Kaptur (D-Ohio) in June, a subcommittee added the provision to a $16 billion bill to fund the Agriculture Department and the Food and Drug Administration and prohibit the FDA from spending money to enforce its prohibition on the importation of drugs it has already approved. Proponents of the measure claim that it will save Americans up to two-thirds on what they spend currently for some medications, while opponents cite the usual safety concerns. The measure, however, is not expected to be a part of the final spending bill.[16]

Another bill gaining support is a bipartisan effort entitled "Pharmaceutical Market Access and Drug Safety Act of 2004." The bill, introduced in the Senate on April 21, 2004, and considered by the Senate Committe on the Judiciary on July 14, 2004, recognizes six findings including:

> *[T]he United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world; and, allowing open pharmaceutical markets could save American consumers at least $38 billion each year.*[17]

Clearly, the focus of this proposed legislation is ensuring lower prescription drug costs for seniors. The bill would allow importation of drugs by waiving certain import restrictions that are currently making that practice difficult under the MMA. However, the bill does much more than simply state that "drugs shall be imported with no restrictions." Rather, it sets up a program whereby certain countries are deemed "registered importers" and "registered exporters." Approved pharmacists and wholesalers in the United States would be able to import from Canada in the

first year of enactment, and then one year after enactment those same pharmacists and wholesalers would be able to import from the European Union, Switzerland, Australia, New Zealand, and Japan. The bill also limits importation to certain qualifying drugs and excludes controlled substances, biological products, infused drugs, intravenously injected drugs, and certain drugs used during surgery.

Another important concern of the bill is consumer safety, as it includes a number of measures to ensure that the importation of drugs is done safely. Those measures include a registration requirement for both exporters and importers and the requirement that each exporter agree to permit the Secretary to conduct onsite inspections, in addition to having access on a day-to-day basis to records of the exporter and samples of exported drugs. Finally, the bill requires the Secretary or employee of the Secretary to inspect the premises of the exporter every three weeks. This bill has received publicity because it represents a bipartisan compromise between 28 Republican and Democratic sponsors and because the nation's largest senior advocacy group, the AARP, recently endorsed it.[18]

General Assembly Legislation

In Virginia, two measures were introduced (neither passed) during the 2004 Session of the General Assembly in support of the importation of drugs from Canada. House Bill 190 directed the Department of Human Resource Management, in consultation with the Office of the Attorney General and the Executive Director of the Board of Pharmacy, to evaluate and permit the implementation of a process for purchasing reduced-cost prescription drugs from Canada for state employees in the State Health Benefits Program. The bill recognizes that prescription drugs from Canada are up to 50 percent less expensive because of price controls, and that prescription drugs comprise the fastest growing segment of health care expenditures, thus warranting consideration of the issue. It was passed by the committee on Health, Welfare, and Institutions in the House but got no further, so the Commonwealth can anticipate at least another year before the issue goes forward, if at all.

House Joint Resolution 199 (2004) called for memorializing Congress to remove current restrictions on the purchasing of prescription drugs from Canada. The General Assembly continued this resolution until 2005, perhaps to give the drug discount card program a chance to get off the ground before Virginia urges Congress to lift the restrictions on importation.

Low-Income Beneficiaries and the "Doughnut Hole"

In an effort to ensure that the United States' poorest citizens have prescription coverage, House Bill 4437 provides for the automatic enrollment of certain low-income beneficiaries in Medicare Savings programs. It also automatically enrolls low-income beneficiaries in the transitional assistance program, making them eligible for the $600 per year in low-income discount card assistance without requiring a separate enrollment process. Each individual automatically enrolled will have 60 days to enroll in a different endorsed discount card, should they feel dissatisfied with the card they have automatically assigned to them. This legislation was recently referred to the House Subcommittee on Health, where it awaits debate.

The MMA does not allow any health plan to assist beneficiaries in reaching the "catastrophic coverage" level, and instead requires out-of-pocket spending to bridge the coverage gap, which is currently between $2,250 and $3,600, before catastrophic benefits (95 percent coverage) kick in. Furthermore, according to indexing provisions, the $3,600 limit is expected to rise to $6,400 by 2013.[19] Critics assert that this coverage gap or "doughnut hole" will disproportionately harm those with chronic health conditions who are most in need of financial relief, and that "it is exactly in this spending range where better coverage of drugs could ultimately help to lower health care spending elsewhere."[20]

Thus, several bills target this issue, including Senate Bill 2339, which allows employers to contribute to drug costs, lessening the out-of-pocket spending for their employees. The bill also allows the provision of wrap-around prescription drug coverage through Medigap to help seniors reach that catastrophic limit with less out-of-pocket expense. As many as 40 percent of all beneficiaries could have drug expenses greater than $2,250 in 2006, the initial implementation year, which would translate into total costs of $70 billion to fill the gap over 10 years.[21] At this point, no legislation has been offered that simply fills in the entire gap and eliminates the doughnut hole.

Various Quality and Cost Control Measures

In addition to allowing the Secretary of Health and Human Services to negotiate prescription drug prices, Senate Bill 2053 directs the Comptroller General to review and report to Congress on the retail cost of prescription drugs in the United States between 2000 and 2003, with an emphasis on the prescription drugs most utilized for individuals age 65 or older. It also directs the Comptroller to review continuously the retail cost of such drugs through April 2006 to determine changes in costs.

So that Congress may make more informed decisions, the bill requires that the Comptroller report annually to Congress comparing the average retail cost in the U.S. for each of the 20 most utilized prescription drugs for individuals age 65 or older with:

1. The average price at which private health plans acquire each such drug;
2. The average price at which the Department of Defense under the Defense Health Program acquires each such drug;
3. The average price at which the Department of Veterans Affairs under the laws administered by the Secretary of Veterans Affairs acquires each such drug; and
4. The average negotiated price for each such drug that eligible beneficiaries have access to under a Medicare prescription drug plan that provides only basic prescription drug coverage.

This review also ensures that drug companies will not arbitrarily raise their prices when the drug discount program goes into effect. Finally, this bill amends the Internal Revenue Code to disallow a tax deduction for advertising expenditures of taxpayers who discriminate against foreign sellers of prescription drugs to domestic customers.

In another attempt to curb Medicare costs, Senate Bill 2130 directs the Secretary of Health and Human Services to warn Congress when excess Medicare prescription drug funding is projected for the fiscal year for which the budget is submitted and directs the President to submit to Congress proposed legislation responding to such a warning within 15 days after the budget submission to Congress. The bill demands that legislation submitted by the President in response to a warning be designed to completely eliminate excess general revenue Medicare funding. This effort is most likely in response to concerns that any cost explosion in the Medicare program must be borne by future generations and that every dollar spent is already borrowed money. By forcing Congress and the President to take action, this bill could help control any unforeseen rise in necessary funding and promote accountability on the part of the President and Congress.

Senate Bill 2512 calls for a streamlined process in the newly created drug discount card program. The bill would require the Secretary of Health and Human Services to choose three cards to be marketed in each region of the nation. This measure is intended to spur competition among companies offering discount cards, as there are more than 73 discount cards offering prices on more than 60,000 drugs. The Secretary would choose cards that provide the greatest access to pharmacies, offer the deepest discounts, and provide access to the widest range of drugs. Finally, the bill would prevent pharmaceutical companies from raising prices above those advertised when seniors signed up for that par-

ticular card and also prevent them from dropping coverage of a particular drug promised to seniors. This would allay the fears of some seniors who have yet to sign up for the card because of those concerns. Currently, the measure awaits hearing and debate in the Senate Committee on Finance.

Education and Public Information

Senate Bill 158 was the one measure on this issue that passed during the 2004 General Assembly session.[22] Anticipating confusion due to the complexity of the MMA, this legislation requires the Commissioner of Health and the Department for the Aging to disseminate to the public information about the drug benefits being provided under the MMA. Further, the law requires the Commissioner of Health and the Commissioner of the Virginia Department for the Aging to develop a strategy, in coordination with the Virginia Area Agencies on Aging, for disseminating to the public information concerning the availability of prescription assistance programs and for training senior citizen volunteers to assist in completing applications for prescription assistance programs and the drug discount cards.

As a result of this legislation, the elderly of Virginia will have concrete assistance in deciding whether or not to sign up for the new drug discount card, as well as assistance with the paperwork once the decision to sign up has been made. The Virginia Department for the Aging provides useful information on its website, including tips on enrolling in prescription drug card programs in Virginia.[23]

Conclusions

Clearly, the addition of a prescription drug benefit to Medicare constitutes landmark social legislation. The growing population of elderly Americans due to the aging baby boom generation and increased costs for prescription drugs are factors that have driven and will continue to drive policy makers in this area. And undoubtedly, attempts to reform this sweeping legislation will continue on both the federal and state level.

The first provisions of the MMA, the temporary discount drug cards, have just recently come on-line and the bulk of the provisions will not take effect until 2006. Meanwhile, citizens should try to stay informed on the current state of the law and how it applies to them, and fortunately there are numerous resources for doing so.

The following is a list of organizations with web-links and telephone numbers where citizens can seek enrollment assistance and find other useful information on the MMA and prescription drug cards:

- Virginia Department for the Aging: http://www.aging.state.va.us/, or 1-800-552-3402
- Virginia Department of Medical Assistance Services: http://www.dmas. virginia.gov/
- Centers for Medicaid and Medicare Services: http://www.cms.hhs.gov/, or 1-800-MEDICARE
- Medicare:http://www.medicare.gov/MedicareReform/
- The American Geriatrics Society: http://www.americangeriatrics.org/
- Health Assistance Partnership: http://www.healthassistancepartnership.org/
- The National Council on Aging: http://www.ncoa.org/

Notes

[1] "How beneficiaries Fare Under the New Medicare Drug Bill," June 2004 Issue Brief, Marilyn Moon, American Institutes for Research.
[2] Letter from the Congressional Budget Office to Congressman Bill Thomas, Chairman, Ways and Means Committee, Nov. 20, 2003.
[3] http://www.medicare.gov.
[4] http://www.cms.hhs.gov/medicarereform/drugcard/sponsorinfostate_summaries_for_drug_card2.pdf.
[5] Id.
[6] Critics of the legislation refer to this coverage gap as the "Doughnut Hole."
[7] CMS Publication No. CMS-1105, January 2004. Note that this out-of-pocket spending threshold will increase in future years pursuant to MMA index formulas.
[8] Id.
[9] "How beneficiaries Fare Under the New Medicare Drug Bill", June 2004 Issue Brief, Marilyn Moon, American Institutes for Research, p 6, citing the Congressional Budget Office (CBO).
[10] CMS Office of Legislation 5/19/04.
[11] "The Medicare-Approved Discount Card Program" (presentation available at: http://www.cms.hhs.gov/partnerships/tools/materials/medicaretraining/english/docs/Mod4Final.ppt).
[12] Health Assistance Partnership: http://www. healthassistance partnership.org.
[13] http://www.medicare.gov
[14] http://www.cms.hhs.gov/medicarereform/drugcard/sponsorinfo/state_summaries_for_drug_card2.pdf).
[15] Press Release, "Conrad Introduces Medicare Mend Bill," (Apr. 22, 2004).
[16] *New York Times News Service,* July 14, 2004.
[17] S.B. 2328, 108th Cong. (2004).
[18] William D. Novelli, *As We See It: Yes to Importation*, AARP Bulletin Online, July-August 2004.
[19] "How Beneficiaries Fare Under the New Medicare Drug Bill", June 2004 Issue Brief, Marilyn Moon, American Institutes for Research p 6; citing Congressional Budget Office (CBO) estimates.
[20] Id. at 3.
[21] Id. at 4.
[22] VA. CODE ANN. § 32.1-23.1 (2004).
[23] http://www.aging.state.va.us.