THE HENRY J. KAISER FAMILY FOUNDATION

THE MEDICARE Rx DRUG LAW

Consumer Protection Issues Raised by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Prepared by:

Geraldine Dallek, M.P.H.

Prepared for:

The Henry J. Kaiser Family Foundation

July 2004

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EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) put into law the most significant changes in Medicare since the program's inception. Designed primarily to lower drug costs for people on Medicare, the new law also sets forth a number of changes that will have significant implications for beneficiaries. The MMA introduces far greater responsibility on the part of elderly and disabled Medicare consumers, creating a new structure that requires beneficiaries to actively engage in a decision-making process regarding their Medicare drug coverage.

Beginning 2006, MMA establishes a new Part D voluntary prescription drug program. Medicare beneficiaries can obtain drug benefits either through new stand-alone prescription drug plans (PDPs) or through private insurers called Medicare Advantage-Prescription Drug (MA-PD) organizations (previously called Medicare+Choice (M+C) plans). Responsibility for prescription drug coverage for individuals with both Medicare and Medicaid will be transferred from state Medicaid programs to Medicare. The program also subsidizes premium and out-of-pocket costs for Medicare beneficiaries with incomes below 150 percent of poverty and limited assets.

The MMA is one of the most complex pieces of health care legislation to pass Congress. This complexity adds to the challenge of program implementation and, more broadly, the program's ability to meet the prescription drug needs of Medicare beneficiaries.

This paper examines several aspects of the new legislation from a consumer perspective; it seeks to identify specific challenges for consumers and offers suggestions to ease the transition as the new drug benefit begins in 2006, simplify the process for people on Medicare, and strengthen consumer protections.

Beneficiary Information Needs

Both prior to and following enrollment, beneficiaries will require a wide range of information, through a variety of sources, in order to make smart choices about their coverage. To make informed decisions about which plan to join, beneficiaries will need clear and detailed information about the health plan choices available to them, including premiums, cost-sharing, and covered drugs. Because beneficiaries are expected to take a more active role in the management of their health care, they will also need real-time information about their coverage and drug spending after they enroll in a plan.

Both prior to and following enrollment, beneficiaries will need a wide range of information. Through a public education campaign, a drug price comparison website on www.medicare.gov, and its 1-800-Medicare hotline, the Center for Medicare and Medicaid Services (CMS) will provide detailed program information to beneficiaries prior to implementation. However, many beneficiaries will find it difficult to compare plans based on website information, especially because prices can change on a weekly basis. Following enrollment, the MMA does not require Part D plans to notify enrollees directly when

formulary drug prices are raised or drugs are switched or dropped altogether from a formulary.

Many beneficiaries will need individual counseling to help them compare Part D options. Adequate funding is necessary for local community organizations—especially for the State Health Insurance Assistance Programs—and for State Medicaid programs to help with this task.

Marketing

In certain markets, Medicare beneficiaries may be inundated with mailings and radio and television advertisements by competing Medicare Advantage plans and stand-alone drug plans. In the past, marketing abuses have been a concern for people on Medicare, many of whom are vulnerable to aggressive sales tactics, without adequate protections in place. Despite past efforts to protect beneficiaries from such practices and strong statements against such practices by CMS in recent months, there is some concern about the potential for selective or aggressive marketing activities when the new Part D benefit goes into effect. Many PDPs will not have directly marketed to the public, let alone to elderly and disabled populations; and individual pharmacies and pharmacists are likely to market specific Part D plans to their customers.

The MMA requires all Part D plans to meet M+C marketing requirements, including the prohibition of door-to-door marketing. The law does not address cold call marketing to beneficiaries and does not establish marketing compensation and training requirements. To help promote enrollment and reduce marketing costs to plans, the MMA permits the Secretary to provide Medicare beneficiary "identifying information" to Part D plans and waive beneficiary privacy protections. The legislation provides no specifics on what the identifying information may or may not include or how information will be kept confidential. Strict and detailed regulations on marketing materials and practices would help protect beneficiaries who may be vulnerable to misleading sales tactics.

Enrollment and Disenrollment

Part D is a voluntary program, meaning beneficiaries can, but do not have to, enroll in a Part D plan. However, beneficiaries who do not have other "creditable" drug coverage for 63 days or longer within a continuous period and fail to join a Part D plan during the open enrollment period will have to pay a late enrollment penalty should they enroll at a later date. Drug coverage is considered "creditable" if its actuarial value equals or exceeds the actuarial value of standard Part D drug coverage. Employer-sponsored group health plans are typically fairly generous and likely to be determined creditable coverage while the standard Medigap drug policies are not likely to meet the actuarial test of Part D coverage.

The late-enrollment penalty is intended to promote participation in the Part D program, however it may disproportionately impact certain Medicare beneficiaries including the low-income population, those who have cognitive impairments, and those with poor literacy or for whom English is a second language. It will also have a negative impact on beneficiaries who

simply do not know about or understand the consequences of delayed Part D enrollment, or those who may feel like they need more time to make informed coverage decisions.

With very few exceptions, those who do enroll during the open enrollment period will be prohibited from switching to a new plan for nine months during the year. This lock-in provision could be especially problematic for enrollees whose medication needs change or whose plan increases prices or drops drugs from its formulary mid-year.

Beneficiaries who are snowbirds and reside in different regions of the country during the course of the year, may have access problems if they enroll in a plan that does not use the same contracting pharmacies in their dual locations. This could result in snowbirds having to pay substantially higher costs if they must obtain drugs from non-network pharmacies during a portion of the year. The establishment of specific guidelines for receiving services from non-network providers are needed to help assist seniors who reside in multiple geographic locations during the year.

Cost-Sharing

A key measure of Part D's success will be its ability to hold down drug costs for people on Medicare. Annual increases in Part D premiums and other cost-sharing requirements are tied to increases in program costs, which are expected to grow faster than increases in Social Security benefit payments for retired workers, which have grown at roughly three percent annually in recent years. Between 2006 and 2013, on average, the Part D monthly premium is projected to increase from $35 to $58, the annual deductible from $250 to $445, and the catastrophic protection threshold from $5,100 in total drug spending to $9,066. If benefit costs increase by roughly 9 percent a year on average, as projected, large numbers of elderly and disabled beneficiaries could find the drug program too expensive to participate, particularly if drug program costs continue to grow faster than income.

Increases in program costs will be a particular problem for enrollees who have not met their out-of-pocket limit. The MMA significantly limits enrollees' ability to obtain help in paying for drugs until the reach the out-of-pocket threshold.

Formularies

Plans that deliver the Part D drug benefit have considerable flexibility in managing their drug benefits to control drug utilization and spending. They may, for example, impose formularies that limit the number of covered drugs to a defined list and provide financial incentives to enrollees to use drugs on their formulary. The MMA requires Part D plans to include in their formularies at least two drugs in each "therapeutic class" or disease category. Part D plans "may" use model guidelines developed by the United States Pharmacopoeia in developing their formularies, but they are not required to follow any specific guidelines. CMS is requiring drug discount card sponsors to follow a defined list of requirements related to formularies including offering at least one reduced price drug in each of 209 "categories" of drugs commonly used by Medicare beneficiaries and ensuring that formularies include discounted drugs needed by "special populations," such as beneficiaries with HIV, mental

illness and cancer. This level of detail is not stipulated for formularies offered by Part D plans.

Consumer groups are especially concerned that formularies will not include the range of drugs enrollees need, Part D plans will switch enrollees' prescriptions to match their formularies, and that formularies can be used to discourage individuals with costly prescription drug needs, such as persons with HIV/AIDs, from enrolling. Safeguards are needed for people with highly sensitive medical conditions – like those on psychotropic medications, for example – for whom a sudden change in medication could be highly destabilizing.

Appeals Process

A functioning appeals process is critical to any publicly-financed program. Part D enrollees can appeal to obtain coverage for a drug not included on a Part D plan's formulary or for an exception to a plan's tiered cost-sharing formulary to obtain a non-preferred drug at a preferred drug's copayment amount.

The MMA largely incorporates the M+C appeals process, including a two-step internal appeals process, appeal to an independent external review organization, and a 72-hour expedited review at each appeals level. However, the Part D appeals process appears more restrictive than the appeals process employed by M+C plans in two respects: (1) the legislation states that *only* enrollees (and not their physicians) can bring an appeal; and (2) there is no requirement that enrollees be notified of their right to an appeal if their drug is removed from a formulary or cost-sharing for a drug is increased during the year. Further, beneficiaries are not granted continued coverage of their prescriptions while an appeal is pending as they are for many other Medicare benefits.

Low-Income Issues

In January 2006 more than 6 million low-income dual eligible beneficiaries with coverage from both Medicare and Medicaid will lose their Medicaid drug coverage. Instead, they are expected to enroll in Part D either through the Social Security Administration or their state Medicaid program. The new law in essence "mainstreams" dual eligibles into Medicare for their drug benefit, rather than treating them differently from all others on Medicare. Unlike for all other health care services provided to dual eligibles, however, Medicaid will not fill in any gaps in prescription drug coverage.

Critical to the success of this policy is a significant effort to transition this population from each of the state Medicaid programs to Medicare (and new Part D plans) for their drug benefits. However, the law does not authorize additional funding to state Medicaid programs to help with this transition for the dual eligible population. The law provides $500 million to the Social Security Administration to help enroll low-income people in the new Part D subsidy program, but does not authorize additional funds for state Medicaid programs to facilitate the enrollment of dual eligibles in Part D plans.

Lack of coordination between the Social Security Administration and state Medicaid programs and the failure to provide added implementation funding to state Medicaid programs have raised fears that dual eligibles could face significant transition problems, potentially disrupting prescription drug regimens for many. There is also concern that the new Part D plans may offer benefits that are less generous compared to many state Medicaid programs because of stricter formularies and somewhat higher copayments, especially for those with incomes above 100 percent of poverty. Further, there is concern that unlike under Medicaid, dual eligibles will not be guaranteed that their prescriptions must be filled even if they cannot meet their copayment obligation.

Dual eligible individuals will have more limited choices than other Medicare beneficiaries. Premiums will be fully subsidized only if eligible beneficiaries join plans with premiums at or below the average for the region. A dual eligible may live in a community with multiple PDPs, but may be effectively restricted to one that has fully subsidized premiums. Assuming more than one plan with fully subsidized premiums is available, dual eligible individuals who fail to choose a plan will be assigned one on a random basis.

The MMA provides a significant subsidy for low-income beneficiaries not eligible for Medicaid (with incomes below 150 percent of poverty and who meet asset requirements). The Secretary has the authority to deem many beneficiaries enrolled in Medicare Savings Programs (which provide Medicaid payments for Medicare premiums and cost-sharing obligations) and in state pharmaceutical assistance programs eligible for Part D low-income subsidies. Deeming and an enrollment "opt-out" provision, which automatically enrolls eligible low-income beneficiaries unless they affirmatively opt-out of the program, would result in higher enrollment among the subsidy-eligible population. Liberalizing or eliminating the asset tests would also reduce barriers to enrollment and help protect low-income beneficiaries from falling through the cracks. CBO estimates that 1.8 million Medicare beneficiaries who meet income test requirements will not qualify for low-income subsidies because of their assets.

Nursing Home Issues

Most nursing homes contract with "institutional" pharmacies that specialize in long-term care facilities. They differ from stand alone prescription drug plans in several ways, including the provision of drugs on a 24-hour a day basis in "blister packs" or "unit dose" packages rather than a 30 or 90 day supply. Yet the legislation is virtually silent on how to meet the specialized prescription drug needs of nursing home patients, simply requiring the Secretary to study the issue and report to Congress. Issues that will need to be addressed include coordinating prescription drug benefits while Part D enrollees are in a nursing home, assessing cost-sharing amounts for nursing home patients who are not dually eligible, and ensuring that beneficiaries who pay for drugs as part of their nursing home stay obtain credit toward their out-of-pocket limit.

Fraud and Abuse Protections

Private entities will administer the new Part D drug benefit. The federal government has a fiduciary responsibility to taxpayers to ensure the fiscal integrity of the program and that funds are properly spent by private plans that contract with Medicare and subcontractors that help administer the new drug benefit. While Medicare has had many years of oversight experience with MA plans, there have been several cases of financial and quality of care violations of government rules over the years, including failure to provide covered benefits and implement a workable appeals process.

Pharmacy benefit managers (PBMs) – entities that now manage prescription drug benefits for millions of American workers – are likely to play a critical role as sponsor or administrators of the new Part D benefit. Today, PBMs typically work on behalf of a client, such as an employer, a union, or insurer to negotiate discounts from pharmacies and rebates and other concessions from drug manufacturers. If PBMs choose to become Medicare drug plan sponsors, they will continue to use these strategies but will also be at financial risk for covered drug benefits – a role that PBMs have not previously played. The Medicare program has no experience overseeing these organizations other than in their role as Medicare-endorsed drug discount card sponsors. Furthermore, as most PDPs are not currently licensed by states as risk bearing entities, the federal government cannot rely on state licensure requirements and oversight to ensure that plans meet minimum standards for financial stability and business integrity.

To the extent that PBMs assume a key role in the new drug benefit, they will require specific guidance about effective compliance that includes internal safeguards against fraud. Requirements set forth in recent settlement agreements with PBMs may offer additional guidance for promoting transparency about drug costs and disclosure of financial incentives.

In addition to setting program standards for plan participation, the Secretary has expansive authority to monitor drug plan sponsors. Under the Secretary's authority, for example, Medicare could be required to conduct yearly financial and business integrity audits of all contracting Part D plans to protect against fraudulent activities. Strong regulatory protections are needed to ensure that past violations are not repeated in the new Medicare drug program.

Conclusion

The MMA introduces a new role and set of responsibilities for people on Medicare that requires individuals to actively engage in a decision-making process about their drug coverage. To facilitate this transition, the Center for Medicare and Medicaid Services (CMS) has begun providing detailed program information to beneficiaries through a public education campaign, a drug price comparison website on www.medicare.gov, and the 1-800-Medicare hotline. However, because of the program's complexity, many beneficiaries will need individualized counseling and assistance. Adequate funding for individual counseling will be essential to transition people to this new program.

Beneficiary education will clearly help the transition to the new drug program. In addition, regulatory and legislative changes may be necessary to further promote consumer safeguards. Regulatory protections can make a difference in how smoothly this massive new program is implemented and how well the new program works for elderly and disabled Medicare populations who are anticipating relief from high and rising drug costs. However, some of the issues and challenges for consumers would likely require a modification of the current law.

CONSUMER PROTECTION ISSUES RAISED BY THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates the most significant changes in Medicare since the program's inception.[1] Beginning 2006, MMA establishes a new Part D voluntary prescription drug program. Medicare beneficiaries will obtain drug benefits either through new stand-alone prescription drug plans (PDPs) or through private insurers called Medicare Advantage-Prescription Drug (MA-PD) organizations (previously called Medicare+Choice (M+C) plans). Responsibility for prescription drug coverage for individuals with both Medicare and Medicaid will be transferred from state Medicaid programs to Medicare. The program also subsidizes premium and out-of-pocket costs for prescription drugs for Medicare beneficiaries with incomes below 150 percent of poverty and limited assets.

To provide some assistance with prescription drug costs prior to 2006, MMA authorized a transitional Medicare-sponsored drug discount card program that began in June 2004. This program offers a $600 drug credit for enrolled low-income beneficiaries.[2] Interim final regulations for the discount card program, issued December 15, 2003, provide some insight into how the Center for Medicare and Medicaid Services (CMS) will address issues surrounding the broader drug program.

Despite fundamental differences over the legislation, supporters and detractors generally agree that beneficiary rights to program benefits must be protected. This paper identifies and examines key consumer protection issues that arise from the new legislation including: beneficiary information, marketing, enrollment/disenrollment, drug benefit package and cost-sharing, appeals process, low-income issues, nursing home issues, and fraud and abuse. A number of the issues discussed in this report, most notably program complexity, the challenge for consumers to make an informed choice of plans because of changing prices coupled with lock-in provisions, high cost-sharing requirements, and the program's impact on beneficiaries eligible for both Medicare and Medicaid can only be addressed through the legislative process. Other consumer protection issues are amenable to regulatory initiatives. How CMS, the program's administrator, addresses these issues will impact beneficiary understanding of, and satisfaction with, their new prescription drug benefit.

PROGRAM COMPLEXITY

At 678 pages, MMA is a fairly complex piece of health care legislation. The Part D drug program is especially challenging for beneficiaries on three counts. First, the prescription drug benefit itself may be difficult for many seniors and persons with disabilities to understand. The standard benefit package requires Part D enrollees to pay (in 2006) an estimated monthly premium of $35, a $250 deductible, 25 percent of the cost of drugs up to an initial coverage limit of $2,250, and all of the costs of *covered* drugs between $2251 and $5100 (referred to as the donut hole). Once this catastrophic limit has been reached (and the enrollee has spent a total of $3600 out-of-pocket in 2006), drugs will be covered at the greater of $2 for generic drugs and $5 for other drugs or a co-insurance of 5 percent.[3] Even for those who are knowledgeable and have experience navigating health insurance coverage, the Part D

benefit may be a challenge to comprehend. Undoubtedly, many Medicare beneficiaries will not understand the on, off, and on again structure of the drug benefit.

Second, plans offering part D benefits may offer a number of different benefit packages as long as they are "actuarially equivalent" to the standard drug package, the deductible is not more than $250, and the enrollee pays $3,600 out-of-pocket before catastrophic coverage begins.[4] Plan formularies, drug prices and network pharmacies will also vary. These differential features across plans are likely to pose difficulties for beneficiaries as they attempt to select a Part D plan for their drug coverage.

The third challenge is that beneficiaries will have to choose whether they want to purchase a prescription drug benefit, and if so, whether to stay in original fee-for-service Medicare and enroll in a PDP or to join a Medicare Advantage plan which covers prescription drugs. Beneficiaries can also enroll in several types of MA plans that do not offer prescription drugs and still enroll in a stand alone PDP. The MA plans authorized by the legislation—HMOs, PPOs, private fee-for-service plans, and medical saving account plans—will not only differ by drug packages, but also by cost-sharing for other Medicare benefits.

In the drug discount card program alone, beneficiaries have a choice of up to 72 discount card sponsors, 39 national and 33 regional plans. The wide range of choices has confused many Medicare beneficiaries,[5] as has the ability of discount card sponsors to change prices on a weekly basis. This confusion may help to explain why initial enrollment in the discount card program has been well below projections.[6]

INFORMATION

Prior to implementation, 41 million Medicare beneficiaries will be learning the nuances of first, the 2004 drug discount card, then one and a half years later, the 2006 Part D program. Educating the Medicare population will demand an extraordinary effort by the federal and state governments. Community-based organizations and others will need resources to assist millions of beneficiaries about the law and their choices.

1. Beneficiary Information Needs

Educating a diverse Medicare population about this massive new program will not be easy. While many beneficiaries are well-informed and sophisticated about their health care options, older beneficiaries, especially those with low educational levels, inadequate or marginal health literacy skills,[7] and those who are cognitively impaired are more likely to have difficulty understanding and navigating the program. With four million elderly people suffering from Alzheimer's disease and 12 million with less than a high school education,[8] sorting through detailed information about drug coverage may be a considerable challenge.

Education Needs Prior to Enrollment: Prior to enrollment, beneficiaries will require a reasonable understanding of the Part D program and of their coverage options. CMS will need to balance the benefits of a simple message, such as the fact that the program is voluntary, with the need to explain program complexities, such as the late enrollment penalty for those who choose not to sign up when they are first eligible. Many beneficiaries do not understand the basic difference between Medicare HMOs and original Medicare, and they are far less able than the under-65 population to interpret simple comparative data.[9]

The MMA requires the Secretary (of Health and Human Services) to provide a range of information to beneficiaries, including comparative information at least 30 days before annual enrollment periods on: (1) plan benefits, (2) monthly premiums, (3) plan quality and performance, (4) required cost-sharing, and (5) consumer satisfaction survey results when available.[10] To meet this requirement, CMS will post a Part D comparison website on www.medicare.gov, similar to the price comparison website posted for the discount card program. The current site allows beneficiaries to compare formulary and pricing information by drug discount card sponsors on brand, generic and mail order prescriptions, as well as plan pharmacy networks and the prices of drugs available at each network pharmacy. This website is intended to bring a measure of transparency to prescription drug price information not previously available. CMS asserts that posting price information will also result in reduced drug prices as discount card sponsors vie for Medicare business.

Unfortunately, in its first months of operation, transparency has been undermined by incomplete and at times, incorrect information[11] and changing drug prices. The ability of sponsors to increase or lower prices on a weekly basis

Table 2
Pharmacy Care Alliance Discount Card Prices: March 3-May 20

Drug, dosage (purpose)	March 3	May 3	May 20	June 2
Vioxx, 25 mg. (arthritis, pain)	$75.88	$85.42	$80.13	$80.63
Effexor XR, 75 mg. (antidepressant)	84.17	91.92	79.66	80.16
Lipitor, 10 mg. (cholesterol)	70.44	70.44	70.44	70.94
Prozac weekly, 90 mg. (antidepressant)	80.62	85.35	89.21	87.99

Source: B. Brubaker, "Shifting Drug Prices Muddy Medicare Card Choice," *The Washington Post*, May 21, 2004, pp. E1, E3.; June 2 update at www.Medicare.gov.

based on changes in manufacturer pricing makes it impossible for beneficiaries to make an informed decision for the longer term on which plan offers the best prices on their prescriptions.

The website also currently lacks some important information. It does not include data on drug formularies and discount cards offered by MA-PD organizations to their members. The site could also be improved by providing an overall comparison or rating of discount card sponsors providing the lowest average prices across drugs (which would have to be updated weekly) and indicate which drugs are discounted.

There is also some question about the extent to which people on Medicare have access to the Internet to use the price compare tool. In a recent survey of seniors and their use of the Internet, thirty-one percent said they have ever gone online to use the Internet or to use email; only 2 percent of these seniors have sought information from the Medicare.gov website.[12] The share of the Medicare population who do not use the internet can obtain a printed price comparison by calling the CMS hotline, 1-800-Medicare,[13] and CMS expects that family and community organizations will help beneficiaries obtain information from the website.

Education and Disclosure Following Enrollment: Once enrolled, beneficiaries will need timely updates on their out-of-pocket prescription drug spending and any changes to a plan's formulary. Although plans are required to give enrollees information on the drug benefits provided,[14] the legislation does not specify how often this information must be provided.

Furthermore, while enrollees are locked-in to their plans for nine months a year (see discussion below), plans can change their formularies, including increasing prices and dropping drugs altogether, at any time during the year if they give "timely" notice on their websites.[15] CMS is requiring that formulary changes be updated weekly on the Medicare price compare database,[16] but unless beneficiaries (and their physicians) affected by these changes are notified directly, the first time they are likely to learn of these changes is when they fill or renew a prescription.

Finally, beneficiaries will need information if a Part D plan changes the medications prescribed by their doctors to other drugs used to treat their condition, a practice known as "drug switching." Part D enrollees will need regulatory protections, including proper notification, if this practice is permitted under the Part D program (see also "Use of Formularies").

2. Strengthening the Information Infrastructure

The new prescription drug program will require a massive outreach and education effort to inform beneficiaries of the new program and help them make smart choices from among the numerous options that will be available to them. Just two months prior to implementation of the prescription drug discount card program, only 38 percent of seniors interviewed knew about the program, and only 18 percent knew about the availability of the $600 subsidy for low-income beneficiaries.[17]

Assistance for beneficiaries with both Medicare and Medicaid (referred to in the legislation as "full benefit dual eligible" beneficiaries) and other low-income beneficiaries eligible for the Part D subsidy will be especially critical (see discussion below). Individuals eligible for Part D low-income subsidies can enroll through their Medicaid or Social Security office, and the legislation requires the Social Security Administration to notify low-income beneficiaries about the program.[18] But, neither state Medicaid programs nor the Social Security Administration is likely to have the staff or resources needed to adequately educate the low-income Medicare population and help them decide among their Part D options.[19] State Medicaid directors have voiced severe reservations about their programs' ability to provide needed outreach and education.[20]

Medicare television ads, the 1-800 hotline, and the price comparison database will not be as helpful for those who need individual counseling. That job will largely fall to the State Health Insurance Assistance Programs (SHIPs) that provide one-on-one counseling to beneficiaries as well as assistance through 1-800 hotlines, and other organizations that work with senior and disabled populations. According to a former head of the Health Care Financing Administration (renamed CMS), SHIPs are "woefully underfunded."[21] The Secretary has increased SHIP funding to help with the massive education effort, but the $21 million earmarked in 2004 and $31.7 million in 2005 (up from $12.5 million in 2003) falls far short of what many policy makers think is needed for the education task at hand.[22] In 2005, federal SHIP funding of $31.7 million translates to only $.77 per Medicare beneficiary.

MARKETING

The MMA envisions a competitive marketplace with PDPs and MA-PD organizations vying with each other to enroll beneficiaries. The new program offers a substantial new market for insurers, pharmacy benefit managers (PBMs), and drugstore chains like Walgreens, CVS, and Eckerd, all of whom began marketing their drug discount cards in May 2004 and will begin marketing their PDPs in November 2005. Medicare Advantage plans, having received a significant increase in funding from the MMA, will also likely expand their marketing activities. In many parts of the country, Medicare beneficiaries will be inundated with mailings and radio and television advertisements by competing plans. The wide array of choices available in some communities and the confusing nature of the Part D program will necessitate strict enforcement of marketing regulations.

1. Marketing Materials

Studies have found that Medicare has not always done a good job of ensuring that private plan marketing materials provide accurate information that is presented in a clear, easy-to-read format. Documented problems with M+C marketing materials include the failure of plan newspaper advertisements to mention eligibility for the under-65 disabled Medicare population; the lack of advertisements in Spanish; the placement of important information in fine print, unreadable by many visually-impaired Medicare beneficiaries; and marketing packages that often fail to meet federal requirements.[23]

Local DC Pharmacy Provides Inaccurate Information about Discount Cards

The author visited her nearest pharmacy on May 12, 2004. A one page brochure available on the counter provided basic information about the discount drug card and referred interested persons to both 1-800-Medicare and www.Medicare.gov. The brochure also states that, "your pharmacy staff can tell you more."

When she asked the pharmacist's assistant about the drug card program, she was given a brochure for PharmacyCare Alliance and told she could fill out the attached application to enroll. She asked if there were any other plans she could apply for and was again referred to the brochure. She then mentioned that she knew of other plans and asked if PharmacyCare Alliance had the best prices. The assistant told her it did.

A May 12 search on www.Medicare.gov proved the opposite was true. Of the 26 plans listed as covering all of four commonly prescribed drugs (Altace, Fosamax, Lipitor and Glucophage) PharmacyCare Alliance had the highest listed prices, $24 a month more than the least expensive plan. Taking into account that the plan's Option A had a yearly enrollment fee of $19 compared to $30 for the least expensive plan, an enrollee would still pay $277 more per year if she enrolled in the plan. At a $30 enrollment fee and $1 less monthly per prescription, Option B still ranked as the most expensive plan listed.

The MMA requires Part D plans to meet existing M+C regulations, which contain several strong protections against marketing fraud.[24] Plans will need to obtain prior CMS approval of all marketing materials. These materials must not be misleading and must provide adequate written descriptions of plan rules, benefits, and appeals processes. Implementing regulations will need to provide greater specificity to guide Part D plans and address concerns about marketing by individual pharmacies or pharmacists promoting a specific plan.

2. Sales Practices

In the early and mid-1990s several reports documented serious problems associated with the marketing practices of Medicare (and Medicaid) HMOs. For example, some HMOs' marketing representatives were found to have enrolled mentally confused or otherwise vulnerable seniors, pressured Medicare beneficiaries to enroll, misled them about HMO benefits and enrollment procedures, and forged beneficiary

signatures.[25] Stricter marketing rules in the 1997 M+C legislation[26] and a reduction in plan marketing associated with M+C program instability led to a sharp decline in inappropriate marketing in the late 1990s.

The MMA raises renewed concerns about marketing. Significantly higher Medicare payment rates will likely rekindle plans' interests in expanding marketing and enrollment Further, while MA organizations are experienced in marketing to the Medicare population, many PDPs will not have directly marketed to the public, let alone to elderly and disabled populations.

In April, the HHS Office of the Inspector General found that proposals by discount drug card sponsors to pay pharmacists a fee for enrolling beneficiaries in their network are likely in violation of the government's anti-kickback statute.[27] Even without financial inducements, beneficiaries seeking their pharmacist's advice on which drug discount plan (and latter Part D plan) to join will likely be steered to a particular contracting plan. Walgreens, for example, exclusively carries drug discount applications for its own discount card and the National Community Pharmacists Association, which also offers a drug discount card, is urging its pharmacies to push the Association's card in anticipation of Part D program implementation. One New Orleans pharmacist includes in all customer bags a discount card pamphlet that states "Trust us to guide your choices."[28]

As noted above, the MMA requires all Part D plans to meet M+C marketing requirements. These include prohibiting door-to-door marketing and engaging in discriminatory marketing activity, such as marketing exclusively in high-income areas, as well as offering enrollment incentives.[29] To protect beneficiaries, MMA implementing regulations could include added marketing protections, such as a prohibition against cold calls, requiring training for marketing agents, and a ban on the co-mingling of Part D information and outreach materials with other marketing materials. The drug discount card regulations provide some, but not all, of these protections.[30]

3. Privacy of Beneficiary Information

Medicare has always protected the privacy of Medicare beneficiaries. However, the MMA, for the first time, permits the Secretary to waive beneficiary privacy protections in order to reduce plan marketing costs, "facilitate efficient marketing," and promote beneficiary enrollment. Specifically, the Secretary "may" give PDP sponsors and MA organizations "identifying information" about Medicare beneficiaries. The legislation provides no information on what this identifying information might include.[31] Although the MMA limits the use of the shared information to Part D marketing and enrollment activities,[32] CMS may have difficulty keeping plans from using it to market other insurance products, such as Medigap policies.[33]

The Secretary has opted not to provide information about beneficiaries to plans offering discount cards. In deciding whether to follow the same policy for Part D, the Secretary will have to balance the need to reduce plan marketing costs with the wishes of beneficiaries who may not want their privacy rights waived.

ENROLLMENT AND DISENROLLMENT

Part D is a voluntary program. Beneficiaries can, but do not have to, enroll in a Part D plan. However, the decision on whether to join a plan – or not – can have far reaching consequences. Beneficiaries who do not have other "creditable" drug coverage and fail to join a Part D plan during the open enrollment period will face financial penalties in the form of increased premiums if they later change their minds. The longer they wait, the greater the premium penalties. Further, with very few exceptions, those who do enroll will be prohibited from switching to a different plan for nine months during the year. This lock-in provision could be especially problematic for enrollees whose medication needs change as for those whose plan's formulary changes mid-year and for snowbirds, who live in a different area for a portion of the year.

1. Late Enrollment Penalty

Although a voluntary program, there are costs associated with not joining a Part D plan. The law penalizes people without comparable drug coverage who fail to sign up initially. Beneficiaries who do not have other "creditable" drug coverage for more than 62 days within a continuous period and fail to join a Part D plan during the open enrollment period will have to pay a late enrollment penalty should they enroll at a later date. Drug coverage is considered "creditable" if its actuarial value equals or exceeds the actuarial value of standard Part D drug coverage.

A beneficiary who delays enrollment will pay the greater of an amount the Secretary determines is "actuarially sound" or one percent of the premium for every month that the individual did not have "creditable" drug coverage for more than 62 days.[34] Beneficiaries who at any time do not have creditable coverage for more than 62 days are also subject to the late enrollment penalty.

Alternative prescription drug coverage is considered creditable if its actuarial value is equal to or exceeds the value of the Part D standard prescription drug coverage. An example of creditable coverage is an actuarially equivalent retiree group health plan.[35] Current Medigap policies H, I, and J, which cover some prescription drugs, would *not* be considered creditable under the law's definition.

Congress imposed the penalty to encourage healthy people to sign up when they first become eligible. If only beneficiaries with high medication costs were to enroll, the program might soon become unaffordable for

Mrs. J Pays Assessed Late Part D Penalty

Mrs. J is a 75 year-old-widow who lives alone on an income of $20,000 a year. Mrs. J has a high school education and is somewhat forgetful. She has about $600 a year in prescription drug costs. Mrs. J has heard about the Part D program from TV ads and has also gotten a number of mailings from Medicare and Part D plans, but finds it all confusing. She has no drug coverage, only a drug discount card, which she thinks is a government-sponsored card. She knows that the program may cost her around $35 a month in the first year, but doesn't know about the penalty for late enrollment.

Mrs. J. opts not to join a Part D plan. Three years after her initial enrollment period, her drug costs increase substantially and she decides to join a plan, only to learn that she will have to pay a penalty of 1% a month for every month she delayed enrollment, for as long as she is enrolled in Part D. This amounts to a 36% higher premium each month for Mrs. J for as long as she gets drug benefits through Part D.

plans, the government, and the individual enrollee.

Although the Medicare Part B program (that covers physician and other out-patient services) has a similar penalty for late enrollment, the Part D cost/benefit calculations on whether to enroll are far more complicated than they are for Part B. Almost all Medicare beneficiaries benefit from Part B because almost all have physician visits and therefore meet the Part B deductible. This would not be the case for Part D where a far larger share of beneficiaries have low drug expenses and potentially face costs (premiums, deductibles, and copays) that exceed the value of the benefit in any given year. Part D enrollees will have to spend an estimated $810 on plan-covered prescription drugs in 2006 before the benefits of plan enrollment outweigh the costs. However, seventeen percent of beneficiaries have less than $250 a year in drug costs.[36]

The Part B penalty is waived for low-income beneficiaries enrolled in the Medicare Saving Programs (MSPs). While the MMA does not similarly waive the penalty for low-income beneficiaries, it does somewhat protect subsidy-eligible beneficiaries; those with incomes below 135 percent of poverty will pay a maximum of 20 percent of the late enrollment penalty for five years; enrollees with incomes between 135 and 150 percent of poverty will pay 1 percent of the sliding premium scale for each month of delayed enrollment.[37]

For beneficiaries with modest incomes who are not eligible for the Part D low-income subsidy but who have little disposable income, the decision to enroll could be a difficult one. Moreover, some beneficiaries may delay enrollment because they are immobilized by the complexity of the program, or, because of age or incapacity, are unable to make an informed enrollment decision.

The *only* exception to the penalty provision applies to beneficiaries whose insurer failed to notify them that their drug coverage was not equal to the benefits offered by Part D plans.[38] Older and disabled beneficiaries who did not understand the information they received about the part D program or the inadequacy of their alternative coverage will not qualify to have the late enrollment penalty waived.

Mr. D and Ms. T are "locked-in" to their Part D plan

Mr. D joins a MA-PD because his heart specialist is in the plan. In early April, his specialist leaves the plan and decides only to serve patients in traditional Medicare. Mr. D would like to continue with his specialist, but if he quits his plan and returns to traditional Medicare, Mr. D. will lose his drug coverage.

Ms. T joined a PDP because it covered all of her medications and her local pharmacy was in the plan. However, during the year, her pharmacy drops out of the plan's network and she discovers that one of her drugs has also been dropped. Ms. T would like to change to another plan that contracts with her local pharmacy, but must wait until January to do so.

2. Lock-In

Medicare HMO and other Medicare private plan enrollees have always had the freedom to change plans during the year for any reason. This freedom to change has been a critical consumer protection, especially for older and disabled beneficiaries who might not have clearly understood their choices or joined a private plan because of marketing irregularities, enrolled only to discover that their

physician or hospital had quit their plan, or felt that they were not getting the care they needed. "Voting with their feet" has been viewed as a way to ensure that the market responds to beneficiary needs and expectations.

Declaring a desire to promote continuity of care, make beneficiaries more accountable for their plan selection and use of health services, and promote program stability, Congress mandated an annual enrollment and disenrollment structure (the "lock-in") for M+C enrollees beginning in 2002. M+C plan withdrawals, benefit reductions, and beneficiary and plan concerns about the "lock-in" led to its postponement until 2005. The MMA further delayed lock-in implementation until 2006.

The MMA limits beneficiaries' freedom to change plans in both the drug discount card and Part D programs.[39] During a transition period, beneficiaries enrolling in a Part D plan will be able to change plans between January and June 30, 2006. Beginning January 2007, lock-in provisions become more restrictive. Beneficiaries can change plans at the end of 2006 (from November 15 to December 31) for enrollment on January 1 of the following year and once during the first three months of the year.[40] However, choice during these three months is limited: If they want to retain drug coverage, PDP enrollees can switch only to a MA-PD organization (but not another PDP) and MA-PD enrollees only to another MA-PD organization or to original Medicare and a PDP.[41] Beneficiaries who have not purchased a Part D plan must wait until the following year to enroll.

Those who enroll in a plan that drops a drug from its formulary or increases the costs of a particular drug during the last nine months of the year will be unable to change plans. While beneficiaries are locked-in to a drug plan, drug plans are not locked in to offering a specific formulary or network of pharmacies.

There are some exceptions to the lock-in provision. Beneficiaries can join or change plans at any time during the year if: 1) they lose other "creditable" prescription drug coverage; 2) they move out of a plan's service area or their plan ceases operations for any reason; 3) they join a MA-PD organization when they first become eligible for Medicare and quit within a year; or 4) their enrollment was the result of "errors in enrollment." The Secretary can also allow changes in "exceptional circumstances," but the legislation provides no explanation of what these circumstances might be.[42]

3. Snow Birds

Large numbers of Medicare beneficiaries who live in cold climates move to milder locations during the winter months. These so-called "snowbirds" typically remain in fee-for-service Medicare and establish relationships with providers near their two homes because Medicare HMOs usually have localized provider networks. How the MMA will address the needs of the snowbird population is an open question.

The Medicare law calls for regional PPO plans to offer drug coverage, but even regional Part D plans are unlikely to have contracting pharmacies in both the summer and winter homes of snowbirds, for example in both Michigan and Florida. Although a large number of national plans are participating in the drug discount program, it is not yet known how many will

participate in the Part D program (the assumption of financial risk in the Part D program may make them less willing to serve the entire nation). Part D plans must provide for "emergency access,"[43] but the legislation is silent on what this means. Will, for example, snowbirds have to pay substantially higher costs if they obtain drugs from non-network pharmacies? The Secretary and /or Congress will need to establish special access and financial protections for seniors who reside in more than one geographic location during the year. The BBA's non-interference clause, which prohibits the federal government from setting prescription drug prices may limit the Secretary's ability to provide meaningful protections for emergency access.[44]

DRUG BENEFIT PACKAGE AND COST-SHARING

The high costs of prescription drugs are a major concern to most Americans, especially the elderly: 57 percent of Americans think prescription drug prices are "unreasonably high"; and by far and away, the elderly consider prescription drug costs their most serious health care problem.[45] The success of the new drug law will depend largely on whether beneficiaries are able to obtain their prescribed drugs at what they view as a reasonable price.

Estimated Rx Drug Spending by Medicare Beneficiaries, 2006

Less than $250	17%
$251-$2,250	35%
$2,250-$5,100	28%
More than $5,100	20%

Source: R. P. Kusserow, "Risk Areas and Best Practices for the Payor Industry, presented at the National Medicare Prescription Drug Conference, Feb. 25-27, 2004.

1. Controlling Prescription Drug Costs

One measure of the program's success will be its ability to hold down drug costs for people on Medicare. Annual increases in Part D premiums and other cost-sharing requirements are tied to increases in program costs, which are expected to grow at a far greater rate than increases in Social Security benefit payments for retired workers, which have grown at roughly three percent annually in recent years. In 2002, prices of drugs commonly used by seniors increased almost 3.5 times faster than inflation.[46] Seven years after Part D implementation, monthly premiums are projected to increase from $35 a month to $58, the annual deductible from $250 to $445 and the catastrophic protection trigger from $5100 in total drug spending to $9000.[47] If benefit costs increase by roughly 9 percent a year on average, as projected, large numbers of elderly and disabled beneficiaries could find the drug program too expensive to participate, particularly if drug program costs continue to grow faster than income.

Studies have found that cost-sharing keeps persons with insurance, especially the elderly and poor, from obtaining needed drugs.[48] A recent Rand Corporation study found that doubling prescription drug co-payments from $16 to $30 reduced the purchase of pain relievers for arthritis by 45 percent; antihistamines by 44 percent; cholesterol-lowing drugs by 34 percent; anti-ulcerants by 33 percent; asthma drugs by 32 percent; high blood pressure pills and anti-depressants by 26 percent; and diabetes medications by 25 percent.[49] If Medicare beneficiaries perceive the cost-sharing requirements as too financially burdensome, they may forgo needed medications.

Congress chose not to limit Part D plan profits (as it does for Medigap plans) nor impose a minimum percentage of price concessions that must be passed through to plan enrollees. The drug discount card regulations also fail to set any limits on plan profits, only requiring that plan sponsors "pass a share" of price concessions to enrollees,[50] and that "some" of the price concessions "should be shared with beneficiaries in the form of lower prices."[51]

2. Filling in the Donut Hole

A particularly controversial feature of the new legislation is the gap in coverage known as the "donut hole." Twenty percent of Medicare beneficiaries are expected to have total drug spending beyond the donut hole in 2006. Paying the entire cost of drugs in the donut hole may be difficult for large numbers of enrollees, who do not qualify for low-income subsidies.

The MMA limits the help Part D enrollees can get in filling the donut hole. Part D prescription drug costs "reimbursed through insurance" are not treated as "incurred" for purposes of meeting the annual out-of-pocket threshold.[52] Thus, the legislation expressly prohibits Part D enrollees from purchasing insurance, such as a Medigap policy, to help pay for Part D cost-sharing and coverage gaps. The legislation also prohibits employer retirement plans from coordinating with Part D and paying retirees' cost-sharing.[53]

It is also unlikely that MA-PD plans will pay for drugs in the donut hole. If they do, they will lose approximately one-third of the federal subsidy, available only after enrollees reach their out-of-pocket threshold. If a plan pays for drugs in the donut hole, plan enrollee will never meet the catastrophic threshold.

The MMA is vague about what other help beneficiaries might obtain to pay their out-of-pocket costs. For example, it appears that only the enrollee and "another person, such as a family member," can help enrollees pay for their drugs until the $5,100 catastrophic limit is reached. The legislation does not address whether churches and other charitable organizations would be considered a person under the statute and thus eligible to help enrollees meet their cost-sharing obligations.[54]

State assistance programs provide financial help with the cost of drugs for older people, people with disabilities or both in over thirty states. Ideally, these state programs will be permitted to pay for all the Part D cost-sharing requirements for low-income program recipients as well as cover off-formulary drugs. However, the MMA prohibits a state pharmacy assistance program from interfering with a Part D plan's "tools for effective cost management." Thus, it is not certain whether these state programs will be able to pay the higher co-pay for a brand drug if a generic drug is also on the formulary or whether state plans can cover drugs not on a PDP's formulary.[55]

Nor does the legislation specify whether other state programs, such as the AIDS Drug Assistance Programs (ADAPs) can pay enrollee's co-insurance. Such assistance is vital for individuals with HIV/AIDS, especially those with low-incomes.

Finally, the degree to which Part D plans limit the number of formulary drugs will impact enrollees' ability to reach their out-of-pocket limit. Non-formulary drugs purchased by Part D enrollees (whether prescription drugs or over-the-counter (OTC) drugs) are not "covered drugs" for purposes of meeting a beneficiary's out-of-pocket threshold.[56]

An increasing number of drugs is approved for OTC status, such as the anti-histamine drug, Claritin. When a drug becomes available for direct purchase, private insurers often drop it from their formulary, although they may cover

Formulary Issues

Inclusion of New Drugs During the Year: After CMS promulgated the discount card regulations in December 2003, the FDA approved a new Alzheimer's drug that falls outside of the single category currently listed to treat the disease.

Too Few Categories: The discount card drug list fails to list an "antianxiety agents" category for Benzodiazepine, which includes drugs commonly used to treat anxiety, such as Zanax, Ativan and Klonopin.

Limited Choice for Some Diseases: Each AIDS anti-viral drug interacts differently with cholesterol lowering drugs, requiring a large number of formulary drugs in this category.

higher cost drugs with similar properties (such as the anti-histamines, Allegra and Clarinex). In these cases, the cost-sharing for the formulary drugs will often exceed the price of the OTC drug. Most state Medicaid programs cover some OTC drugs if they are prescribed by a physician and substitute for formulary drugs requiring a high co-insurance or co-payment.[57]

3. The Use of Formularies

The use of formularies or preferred drug lists is a common feature of today's insurance market.[58] By limiting the number of covered drugs, public and private insurers, and PBMs on behalf of insurers, are able to negotiate greater discounts from manufacturers whose drugs are included on the list. Plans design benefit packages to include financial incentives for patients to use less expensive drugs on the plan formulary. These "incentive-based formularies" often use a three-tier copay structure: generic drugs have the lowest copay; brand-name formulary drugs with no generic equivalent, an intermediate copay; and non-formulary drugs, the highest co-pay. Tiered formularies promote the use of lower cost generic drugs, which have the same active ingredients as their brand counterparts.[59]

The use of formularies requires a delicate balancing act: the more drugs on a formulary, the higher the costs of covered drugs; the more restrictive the formulary, the less likely enrollees will have available to them the drugs they need.[60] Formularies are of particular concern to individuals whose diseases might require the availability of a large number of drugs in each therapeutic class. Most insurers have an exceptions policy, but restrictive drug formularies often require enrollees to change drugs or to try formulary drugs before non-formulary or non-preferred drugs can be prescribed.

The tiered nature of most formularies also raises the possibility that Part D plans will use them to discourage individuals with costly prescription drug needs, such as persons with HIV, from enrolling. Part D plans could, for example, place high priced HIV drugs in tier three of their formulary and require very high cost-sharing for drugs in this category. CMS has not in the past effectively prevented M+C plans from manipulating cost-sharing in ways that adversely affect enrollees with chronic and life-threatening conditions. In 2002 and 2003, some M+C plans increased costs on specific services most likely to be used by enrollees with high-cost conditions, such as hospital care, oxygen, dialysis, chemotherapy, and radiation therapy.[61]

The MMA requires Part D plans to include in their formularies at least two drugs in each "therapeutic class" or disease category. Part D plans "may" use model guidelines developed by the United States Pharmacopeia in developing their formularies.[62] CMS is requiring that discount card sponsors (1) offer at least one reduced price drug in each of 209 "categories" of drugs commonly used by Medicare beneficiaries; (2) make available lower cost generic drugs in the majority of categories; (3) ensure that formularies include discounted drugs needed by "special populations," such as beneficiaries with HIV, mental illness and cancer; and (4) include both short-acting and long-acting medications in therapeutic classes.[63] In addition, CMS has required discount card plans to offer three drugs in each category.[64] Given the legislative leeway granted Part D plans in developing their formularies, CMS may not have the authority to impose similar requirements for the Part D program.

The legislation also prohibits the Secretary from approving any Part D plan whose "design" or "benefits (including any formulary and tiered formulary structure) are likely to *substantially* discourage enrollment by certain part D eligible individuals."[65]

Despite these considerable written protections, additional concerns remain. How, for example, will first discount card sponsors and later Part D plans respond when a new category of drugs or a new drug with proven advantage over existing drugs is approved by the FDA during the year?[66] Will individuals with specific conditions, such as AIDS and mental illness, have access to the panoply of drugs needed to treat their conditions?[67] Will Part D plans limit drugs to their on-label use, thus preventing people with rare conditions from obtaining drugs which might benefit them? How will CMS interpret the prohibition against plan designs that "substantially" discourage enrollment by certain beneficiaries? Should there be a limit in the spread of cost-sharing between formulary tiers?

Finally, the MMA does not prohibit Part D plans from replacing one formulary drug with another to maximize profits through higher rebates, even when the replacement drug is more expensive, requires higher cost-sharing, and provides no discernable benefit to the enrollee.

THE APPEALS PROCESS

Any formulary, by definition, will result in the exclusion of some drugs. To address concerns that restrictive formularies prevent enrollees from obtaining needed drugs at reasonable prices, the MMA provides for an appeals process. The MMA appeals process is protective of enrollees' rights. It does, however, lack some of the protections afforded Medicare Advantage enrollees appealing other program benefits.

1. Part D vs. Medicare + Choice Appeals Protections

A functioning appeals process is critical to any publicly-financed program. Until 1997 M+C legislation and litigation induced changes, the HMO appeals process failed to meet beneficiary needs: M+C enrollees often did not know they had the right to appeal,[68] plans failed to provide timely appeals, and appeals were sometimes arbitrarily denied.[69] It is for this reason that a strong formal appeals process is a vital component of the Part D benefit.

Part D enrollees can appeal: (1) to obtain coverage for a drug not on a Part D plan's formulary; or (2) for an exception to a plan's tiered cost-sharing formulary to obtain a non-preferred drug at a preferred drug's co-pay. In the first instance, an enrollee might appeal to obtain a cholesterol-lowering drug not on their plan's formulary. In the second instance, an enrollee might appeal to obtain a non-preferred brand drug with a $50 co-payment for the $5 co-payment charged for the generic substitute. Requests for exceptions to a plan's tiered cost-sharing formulary and appeals can only be lodged if a prescribing physician determines that a preferred or formulary drug "would not be as effective" and/or "would have adverse effects for the individual" compared to a non-formulary or non-preferred drug.[70]

The MMA largely incorporates the M+C appeals process, including a two-step internal appeals process (14 days for an initial determination and 30 days for a reconsideration request) and for an appeal to an independent external review organization. Each of the appeal stages provides for an automatic 72-hour expedited review for physician requests. M+C plans must also grant an enrollee's request for an expedited review if it determines that the standard timeframe could jeopardize an enrollee's life, health, or ability to regain maximum function.

The Part D appeals process appears more restrictive than the appeals process employed by M+C plans in two respects. First, the legislation states, "only the part D eligible individual shall be entitled to bring…an appeal."[71] In the M+C program, beneficiary representatives, including physicians and nursing homes, can submit an appeal on their behalf. If physicians cannot appeal on behalf of their patients, the M+C requirement that plans provide expedited review for all physician requests would be superseded.

Second, Part D notification of appeals rights is more limited than in the M+C program. The MMA requires Part D plans to annually notify enrollees of their appeal rights. However, unlike requirements for M+C plans (which must notify enrollees of their appeal rights when a benefit is terminated or reduced), PDPs do not have to give enrollees affected by a change in a plan's formulary (e.g., the dropping of a drug from the formulary or a change in the tiered status of a drug) notice of their right to appeal. Unless notice of appeal rights is more broadly

disseminated, Part D enrollees are unlikely to learn that they have the right to appeal a change in their prescriptions.

The M+C non-expedited timeframe of 14 days for an initial determination and 30 days for a reconsideration request may prove to be excessive for individuals in need of non-formulary drugs, or if a drug has been dropped from the formulary. Regulations will need to clarify who can appeal on behalf of an enrollee and under what circumstances an expedited review is granted. Regulations are also needed to clarify the standards by which Part D plans and external appeals reviewers can deny appeals.

2. Provision of Drugs During the Appeals Process

As noted above, Part D plans are permitted to drop formulary drugs during the year as long as they provide prior notice through their websites. Thus, even if beneficiaries appeal a plan's decision to change its formulary mid-year, they would have to pay out-of-pocket the entire costs of their drugs during the appeals process or take a substitute drug. Enrollees in need of a non-formulary drug would be faced with a similar dilemma. Low-income beneficiaries would likely be unable to assume the costs of uncovered drugs. Today, some Medicaid programs provide for an emergency supply of non-formulary drugs during the appeals process and Medicare requires hospitals, nursing homes, and home health agencies to continue providing services during an expedited appeal.

LOW-INCOME ISSUES

MMA subsidizes prescription drug costs for two groups: "full benefit dual eligible individuals" and individuals not eligible for full Medicaid but with incomes below 150 percent of poverty who meet Part D assets tests.

Additional Help with Rx Drug Costs for Low-Income People on Medicare

People on Medicare Who Also Have Full Medicaid Benefits (Dual Eligibles) will pay in 2006:

- No premium
- No deductible
- Copayments as follows:
  - Nursing home residents: No copayments
  - Individuals below poverty level: $1/generic; $3/brand name drug
  - Individuals above poverty level: $2/generic; $5/brand name drug
- No copayments after individual spends $3,600 out-of-pocket on drugs

People on Medicare with Incomes Below 135% of Poverty (about $13,000/individual; 17,000/couple) and Assets Below $6,000 per individual/$9,000 per couple will pay:

- No premium
- No deductible
- Copayments of $2/generic and $5/brand name drug
- No copayments after individual spends $3,600 out-of-pocket on drugs

People on Medicare with Incomes Below 150% of Poverty (about $14,000/individual; $19,000/couple) and Assets Below $10,000 per individual/$20,000 per couple will pay:

- Sliding-scale premium
- $50 deductible
- 15% coinsurance up to $5,100 in total drug spending (= $3,600 out-of-pocket drug spending)
- Copayments of $2/generic; $5/brand name drug after individual spends $3,600 out-of-pocket on drugs

Unlike state Medicaid programs, the legislation divides the dual eligible population into three groups. Full benefit dual eligible beneficiaries with income at or below 100 percent of poverty pay no premiums and have co-pays of $1/generic and $3/brand drugs, but those with incomes above 100% of poverty will have co-pays of $2/generic and $5/brand drugs. Dual eligible institutionalized patients have no cost-sharing.[72]

The MMA provides subsidies for some 7.6 million low-income Medicare beneficiaries who are not eligible for Medicaid. In 2006, those with incomes below 135 percent of poverty and with assets below $6,000 for an individual and $9,000 for a couple will pay no premiums and have co-pays of $2 generics/$5 brand drugs; those with incomes between 135-150% of poverty and assets of $10,000 per individual and $20,000 per couple will pay premiums on a sliding fee scale, a $50 annual deductible, and 15% co-insurance up to the $3,600 out-of-pocket threshold (in 2006) and $2 generic/$5 brand co-pays thereafter. Cost sharing for the latter group will increase with costs of the Part D program.

1. Dual Eligible Enrollment Issues

Dual eligible individuals will have to join a Part D plan to obtain prescription drug coverage if, as a practical matter, they want to continue to receive drug coverage. This population will need substantial help during the transition period when responsibility for prescription drug coverage is transferred from state Medicaid programs to Medicare in January 2006; more than 6 million low-income beneficiaries will have to join a Part D plan for the first time and may have to change some prescriptions to conform to their Part D plan's formulary.

Coordination Issues: Low-income beneficiaries can be enrolled in part D through either the Social Security Administration or their state Medicaid office. The logistics of enrolling so many low-income beneficiaries, many of whom are poorly educated, disabled, or unable to speak or read English are a major challenge. Unlike other Part D eligible beneficiaries, individuals on full Medicaid do not have the option of using the 5-month annual coordinated election period (November 15, 2005-May 15, 2006) to make an enrollment decision. Instead, to keep uninterrupted drug coverage, dual eligible individuals must enroll by January 1, 2006, the date state Medicaid programs cease to pay for prescription drugs for this group.

To ensure that all full-benefit dual eligible individuals are automatically enrolled will require a degree of coordination among states and the federal government that has never previously occurred. Neither the Social Security Administration nor state Medicaid offices has a complete listing of individuals eligible for Part D as full benefit dual eligibles.[73] The MMA appropriates $500 million to the Social Security Administration to help enroll low-income people in the new Part D subsidy program but has not authorized additional funding (above the federal match) for state Medicaid programs to facilitate the enrollment of dual eligibles in Part D plans. Between 2004 and 2006, states are collectively expected to lose $1.2 billion as a result of these new administrative responsibilities and other Medicaid provisions in the MMA.[74]

Limited Choice: Low-income individuals will have less choice than other Medicare beneficiaries. Premiums are fully subsidized only if eligible beneficiaries join plans with premiums at or below the average for the region. Thus, there may be three or four PDPs in a community, but only one with fully subsidized premiums. Assuming more than one plan with fully subsidized premiums is available, dual eligible individuals who fail to choose a plan will be assigned one on a random basis.[75]

States have faced a wide range of problems associated with mandatory Medicaid managed care enrollment, including inadequate enrollment staff; difficult-to-understand enrollment materials; failure to provide appropriately translated materials in languages other than English; and failure to match beneficiaries with plans that included their primary providers.[76]

Default enrollments raises the specter of large numbers of poor beneficiaries enrolled in plans that do not meet their needs. For example, mentally ill beneficiaries may be enrolled in Part D plans that do not cover their anti-depressant drugs. Although assigned enrollees can change to another Part D plan or appeal to have their drug covered, many poor and disabled beneficiaries will not have the wherewithal to take these actions nor will they necessarily have personal assistance in making these decisions.

2. Enrollment Issues for Non-Medicaid Low Income Beneficiaries

Ensuring that a substantial share of beneficiaries eligible for the part D subsidy enroll in a Part D plan will require extensive education and effective outreach efforts. Unfortunately, if the history of the Medicare Savings Programs (MSPs) is any guide, large numbers of subsidy-eligible beneficiaries will not learn of the program or will face a late enrollment penalty when they do join. Medicare Savings Programs provide Medicaid payments for Medicare premiums and cost-sharing obligations. Sixteen years after the first and most generous of these programs was enacted, only 57 percent of eligible beneficiaries were enrolled in the two most generous MSPs.[77] A 2002 Social Security mailing to 16.4 million Medicare beneficiaries potentially eligible for an MSP resulted in only an additional 0.5 percent increase in enrollment.[78] These figures suggest there may be real challenges in enrolling Part D subsidy-eligible beneficiaries in the drug program, even with education and outreach efforts in place.

Deemed Eligibility: A major problem with the MSP program is the paperwork involved in the eligibility determination. To increase enrollment of subsidy-eligible individuals, low-income enrollees in state pharmaceutical assistance programs and in MSPs could be automatically deemed eligible. The Secretary is required to deem all MSP beneficiaries as Part D subsidy-eligible if state MSP eligibility requirements are "substantially the same" as the low-income Part D subsidy requirements.[79] The Secretary also has the authority to deem MSP beneficiaries in states whose eligibility requirements do not meet this standard if taking this action does not result in "significantly differences" in the number of people eligible for the subsidy.[80]

How the Secretary will define "substantially the same" and "significant differences" and whether all MSP beneficiaries will be deemed automatically eligible for the Part D subsidy are open questions. Twenty-one states, including Florida, have less restrictive MSP rules regarding assets than Part D requirements, including four states that have eliminated asset tests altogether.[81]

CMS has decided to deem *and automatically enroll* in the $600 transitional assistance program eligible Medicare beneficiaries enrolled in state pharmaceutical assistance programs. A similar decision has not been made on behalf of low-income beneficiaries enrolled in MSP programs.[82]

Opt-In/Opt-Out Issue: Despite the best efforts of the federal and state governments and community-based organizations, many low-income beneficiaries, even if deemed eligible, will not learn of or understand the enrollment process. As of April, two months prior to the implementation of the discount card program, only 18 percent of seniors and 14 percent of the general public were aware of the $600 subsidy for low-income seniors.[83]

Enrollment rules and requirements could make a large difference in the numbers of low-income beneficiaries who elect Part D. To encourage Medicare beneficiaries to enroll in the voluntary Part B program, Medicare adopted an "opt out" rather than an "opt in" procedure. Individuals first becoming eligible for Medicare have to notify the Social Security Administration if they wish to decline Part B coverage, otherwise, they will be automatically

enrolled. In contrast, Part D employs an "opt in" provision, which means that beneficiaries have to enroll in the program, even if they are deemed eligible.

An opt-out policy limited to persons eligible for the Part D subsidy (MSP and state pharmaceutical assistance program enrollees) could enroll only those beneficiaries who do not choose a plan. Beneficiaries who are opted in and assigned a plan could change plans or decide to opt out, thus retaining the voluntary nature of the program.

Assets Test: Requiring beneficiaries to meet an asset test for the Part D subsidy program is controversial. Proponents of assets tests argue that low-income beneficiaries with significant savings or other resources should not be eligible for tax subsidized programs. However, advocates for the low-income elderly population and many state Medicaid administrators agree that asset tests significantly add to the administrative and cost burdens of enrolling eligible program beneficiaries, require low-income beneficiaries to use up most of their savings to become eligible, and make the application process much more cumbersome for beneficiaries, keeping them from obtaining coverage.[84] The Congressional Budget Office estimates that 1.8 million Medicare beneficiaries who meet MMA income test requirements will not qualify for the low-income subsidies because of their assets.

3. Less Generous Benefit for Dual Eligible Beneficiaries Compared to Medicaid

The Part D benefit is generally more restrictive than prescription drug benefits available through state Medicaid programs in three respects that will likely reduce access to prescription drugs: limited formularies, higher co-payments and the lack of protections for beneficiaries who can't pay their cost-sharing.

Mr. L. Has Problems Filling His Prescriptions

Mr. L is a dual eligible beneficiary with bipolar disease. He lives on an income of $10,000 a year, slightly above the poverty line. In December 2005, Mr. L receives notice that he must use a new card to obtain his medications. When he next visits his local pharmacy for a prescription refill, his pharmacist tells him that he has to go to another pharmacy 5 blocks away and that his doctor will need to send in new prescriptions for his mental illness, cholesterol and blood pressure medicines.

When Mr. L calls his doctor, the nurse tells him that he will also need to switch one of his drugs, but that if he wants his old medicine, he can appeal. Mr. L. decides to try the new prescription, but when he goes to the pharmacy, learns that he has to pay $12 for the three prescriptions. He decides not to fill his prescriptions.

Limited Formularies: Part D plan formularies may be more restrictive than state Medicaid formularies. Although some state Medicaid programs have imposed significant limits on their prescription drug programs, other states provide a broad array of drugs in their Medicaid programs.[85] Moreover, because the MMA limits the premium subsidy to at or below the average PDP premium for the region, low-income beneficiaries may be enrolled in plans with more restrictive formularies.[86]

Higher Out-of-Pocket Costs: Increases in prescription drug cost-sharing and tiered formularies have been shown to reduce compliance with drug regimens, especially among the poor in ill health.[87] Dual eligible beneficiaries enrolled in Part D will pay higher out-of-pocket costs for their drugs than required by most Medicaid programs, especially beneficiaries with incomes slightly above the poverty level, who will pay $2 per generic and $5 per brand drug.[88] These co-payments will rise with

increases in program costs—an estimated 9 percent a year—although beneficiary income is tied to increases in Social Security (which have recently averaged 3 percent a year). States could pay for beneficiary co-payments (and for drugs not covered in plan formularies) but would receive no federal matching funds to help finance these costs.

Guaranteed Prescriptions: Unlike Medicaid, the MMA does not guarantee that beneficiaries who cannot meet their co-payment obligation will receive their prescriptions. Pharmacies participating in the drug discount card program may waive co-insurance for enrollees receiving the $600 transitional assistance,[89] although implementing regulations permit this only in limited circumstances.[90]

NURSING HOME ISSUES

Nursing home beneficiaries obtain their prescriptions differently than the non-institutionalized population. Most nursing homes contract with "institutional" pharmacies that specialize in long-term care facilities. These pharmacies differ from PDPs in several ways, including the provision of: prescriptions in daily "blister packs" or "unit dose" packages rather than a 30 or 90 day supply; and drugs on a 24-hour a day basis. Institutional pharmacies are like PDPs in that they maintain formularies and negotiate price discounts in exchange for including particular drugs in their formularies. [91]

Nursing Home-Part D Coordination Issues

"Assume there are two Part D plans in an area; that some dually eligible residents in the same nursing facility select one of these plans and some another; that the nursing facility uses an institutional pharmacy and consulting pharmacist that do not contract with either of the Part D plans; and that both Part D plans have formularies and dispensing procedures that are different from one another and different from those of the facility's institutional pharmacy."
Source: A. Schneider *Dual Eligibles in Nursing Facilities and Medicare Drug Coverage* (Washington, D.C.: The Kaiser Commission on Medicaid and the Uninsured, Nov. 13, 2003)

The MMA is virtually silent on how to meet the specialized prescription drug needs of nursing home patients, simply requiring the Secretary to study the problem and report recommendations to Congress by July 2005.[92] CMS will likely have to make decisions about integrating nursing home prescription drug practices with the Part D program well prior to this July deadline.

Issues that will need to be addressed include:

- How will prescription drugs be coordinated for beneficiaries who are transferred from home, to a hospital, to a nursing home, to a rehabilitation hospital back to home?
- How will Part D cost-sharing work for Medicare covered nursing home stays? Beneficiaries pay co-insurance after the first 20 days of a Medicare-covered nursing home stay. As this co-insurance covers some of the costs of prescription drugs, will beneficiaries get credit toward their out-of-pocket limit?
- How will cost-sharing work for nursing home residents who are not on Medicaid and who do not quality for Medicare's skilled nursing facility benefit?
- Will more than one Part D plan be offered to nursing home patients, and if so, who will choose if the nursing home resident is unable to make the decision?

These questions are especially salient as two weeks prior to implementation of the drug discount program, CMS had not yet determined how to implement the program for nursing home patients and provide eligible nursing home beneficiaries with the $600 subsidy.[93]

MMA provisions and implementing regulations for the drug discount card allow the secretary to negotiate with pharmacies that serve long-term care facilities.[94] The Secretary has endorsed two national pharmacies to provide discounts to the nursing home population. How the discount card works for nursing home patients will likely provide some indication of the challenges associated with ensuring nursing home beneficiaries have adequate access to needed prescriptions.

FRAUD AND ABUSE PROTECTIONS

The MMA is built on a foundation of choice. The legislation envisions a least one PDP sponsor and one MA-PD in each of 10-50 regions. To make choice a reality, Medicare faces two potentially conflicting goals—to encourage PDP participation while at the same time ensuring that sponsors meet a high ethical and financial bar. Recent cases suggest many future sponsors could fail to meet these criteria.

Many PDP sponsors will be PBMs that already manage prescription drug benefits for millions of American workers, negotiating discounts, rebates and other concessions from drug manufacturers. However, as PDP sponsors, PBMs will, for the first time, be at financial risk for covered drug benefits – a substantially new role for PBMs.

Medicare has had many years of oversight experience with MA plans, and even here the record, especially in earlier years of the Medicare HMO program, is replete with financial and quality of care violations of government rules, including failure to provide covered benefits and implement a workable appeals process.[95] Medicare has no experience with oversight of PDPs. Furthermore, as most PDPs are not currently licensed by states as risk bearing entities, the federal government cannot rely on state licensure requirements and oversight to ensure that plans meet minimum standards for financial stability and business integrity.

In the last few years, PBM operations have come under increased scrutiny by the federal and state governments, unions, large employers and insurers. In 2003, the Justice Department charged Medco Health Solutions, the largest PBM, with annual revenues of more than $34 billion, with fraud, falsifying records and making false statements in the Federal Employee Health Benefit Program (FEHBP).[96] Specifically, Medco was charged with destroying prescriptions, shipping prescriptions with too few pills, switching patients' medications without their knowledge or consent, billing patients for drugs that were never ordered, accepting kickbacks from manufacturers to use their products and creating false records of contacts with physicians. The Medco case was settled in April 2004 when the company agreed to pay $29 million to 20 states and make significant changes in its operations.[97] Express Scripts, the nation's third-largest PBM, is also under an integrity cloud.[98]

One U.S. Attorney who has investigated PBMs believes that the lack of HHS oversight experience in the prescription drug arena coupled with the scope of the new program presents "huge new opportunities for fraud."[99] To choke off these opportunities, the Secretary will have to set high standards for Part D participation and closely monitor contracting PDP sponsors.

The MMA requires PDPs to be either licensed by a state or, if a state licensing process does not exist for these entities, meet "financial solvency" and "capital adequacy standards" established by the Secretary.[100] In addition to setting program standards for plan participation, the Secretary has expansive authority to monitor PDP sponsors, but the MMA provides little detail on how this authority should be used. For example, the Secretary "may" audit the financial statements and records of Part D plans, but the MMA does not specify how often audits should be performed.[101]

The discount card drug program and implementing regulations give some indication of the criteria that will be used for participation in the Part D program. Applicants for discount card sponsorship must have three years of experience, serve at least one million individuals and demonstrate a "satisfactory record" of "financial stability and business integrity."[102] How the Secretary will define business integrity is not evident. Although FEHBP did not renew the Medco contract in 2004 and the federal civil fraud case is still pending in federal district court in Philadelphia, the Secretary nevertheless approved the company as a discount card sponsor.

The Secretary will need to assess whether allegations of and/or settlements or judgments against PBMs for fraud and abuse claims preclude their participation in the Part D program, where these companies will be at financial risk. The Secretary also has the authority to conduct a yearly audit of PDPs and to require that they institute internal procedures to prevent fraud.

Only 13 percent of Americans believe the pharmaceutical industry is generally honest and trustworthy and 57 percent think the industry should be more tightly regulated.[103] Strong regulatory protections are needed to ensure that the past violations of fraud and abuse laws are not repeated in the new Medicare drug program.

Endnotes

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[2] Beneficiaries not on Medicaid with an income between 100-135 percent of poverty will pay 10 percent of their drug costs; those with incomes below 100 percent of poverty will pay 5 percent.
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[5] J. Leland, "73 Options for Medicare Plan Fuel Chaos, Not Prescriptions," *The New York Times*, May 12, 2004, pp. A1, A27.
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[32] MMA Sec. 1860D-1(b)(4); H.R. Rep. No. 108-391, p. 432.
[33] Several MA organizations, including HMOs, PPOs and Private-Fee-For Service plans also offer Medigap insurance..
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[35] MMA Sec. 1860D-13(b)
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[89] MMA, § 1860D-31(g)(4)(A).
[90]The waiver cannot be advertised; the co-insurance cannot be routinely waive; and only waived after determining that the beneficiary is in financial need or collection efforts have failed. 68 Fed. Reg. p. 69863.
[91] Eighty percent of nursing home beds are supplied by institutional pharmacies that specialize in long term care facilities. A. Schneider, Dual Eligibles in Nursing Facilities and Medicare Drug Coverage (Washington, D.C.: The Kaiser Family Foundation, Nov. 13, 2003.)
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The Henry J. Kaiser Family Foundation:
2400 Sand Hill Road
Menlo Park, CA 94025
(650) 854-9400
Facsimile: (650) 854-4800

Washington, D.C. Office:
1330 G Street, N.W.
Washington, DC 20005
(202) 347-5270
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