THE HENRY J. KAISER FAMILY FOUNDATION

THE MEDICARE DRUG BENEFIT

The Role of Part D for People with HIV/AIDS: Coverage and Cost of Antiretrovirals Under Medicare Drug Plans

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INTRODUCTION

Medicare has historically been an important source of health insurance coverage for many people with HIV/AIDS and stands to play an even greater role as a result of the new Medicare Part D prescription drug benefit, given the importance of pharmaceutical treatment for this population. Even before Part D took effect, Medicare was the second largest source of federal spending on HIV/AIDS care in the United States, accounting for approximately one quarter (26%) of spending in FY 2006.[1] Most Medicare beneficiaries with HIV/AIDS are under age 65 and qualify because they are eligible for Social Security Disability Insurance (SSDI) benefits, although some also qualify as seniors. Medicare is estimated to cover almost one in five (19%), or approximately 100,000, people with HIV/AIDS in care in the United States.[2]

As of January 1, 2006, all people on Medicare, including those with HIV/AIDS, were given access to the new Part D benefit, which is offered by private, stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans.[3] Under Part D, beneficiaries have access to dozens of plans in each state, each with a different monthly fee (premium), list of covered drugs (formulary), and cost-sharing amounts for covered drugs. Like other Medicare beneficiaries, those with HIV/AIDS encountered a set of potentially complex tasks, including deciding by May 15, 2006 whether to enroll in a Medicare drug plan and, if so, identifying the plan that offered the best and most affordable coverage for the drugs they take. In addition, they could consider whether they qualify for additional low-income assistance under the Medicare drug benefit or are eligible for supplemental coverage or assistance from other programs, including Medicaid, the nation's public health insurance program for low-income Americans, or the AIDS Drug Assistance Program (ADAP) of the Ryan White CARE Act, which provides care and services to people with HIV/AIDS who are uninsured or underinsured.

To gain a better understanding of these issues, this study provides an in-depth look at the cost and coverage of drugs used by people with HIV/AIDS under Medicare's new stand-alone prescription drug plans, with a particular focus on antiretroviral (ARV) medications. ARVs are of critical importance to people living with HIV/AIDS. When taken in combination (usually of three or more drugs), they comprise what is known as "highly active antiretroviral therapy" (HAART), which has been responsible for dramatic declines in morbidity and mortality among people with HIV in the United States.[4,5] A typical HAART regimen includes the use of multiple ARV medications per day, and patients are often faced with the need to switch ARV treatment regimens over time[6] due to side effects, adverse drug interactions, or regimen failure.[7] ARV medications are also expensive, with a typical regimen estimated to cost[8] approximately $14,000 - $15,000 per patient per year, although costs may be higher for more complicated regimens. As a result, people with HIV/AIDS often rely on public insurance and other programs to obtain medications or assist with medication payments.[9] Indeed, prior to 2006, most Medicare beneficiaries with HIV/AIDS relied on Medicaid[10] or ADAP[11].

METHODS

To assess the coverage of approved ARVs and recommended ARV treatment regimens and associated out-of-pocket costs under Medicare Part D plans for people with HIV who do not qualify for low-income subsidies, we collected data from the Medicare Prescription Drug Plan Finder on Medicare.gov during the week of May 22, 2006. (See text box on page 2 for a description of the low-income subsidy.) The Medicare Plan Finder is a Web-based tool

designed by the federal Centers for Medicare and Medicaid Services (CMS) to assist Medicare beneficiaries and others in comparing drug plan options by providing information about specific drugs covered by each drug plan, by form and dose level. Because the Plan Finder requires users to search by zip code, we focused our analysis on 47 stand-alone PDPs available in the State of Maryland; most of these plans are also available nationwide or in almost every other state.[12,13]

The drug benefit includes substantial premium and cost-sharing subsidies for Medicare beneficiaries with low incomes and modest resources, including beneficiaries eligible for full Medicaid benefits (dual eligibles), who previously had drug coverage through their state Medicaid program. These low-income subsidies are intended to reduce or eliminate enrollees' out-of-pocket expenses associated with the drug benefit, including premiums, deductibles, copayments, and costs in the coverage gap (the so-called "doughnut hole").

We included all 27 brand-name ARVs that have been approved by the U.S. Food and Drug Administration (FDA), three of which represent combinations of individually approved ARVs, in this analysis.[14,15] In addition, we included two generic ARV equivalents approved by the FDA for use in the U.S. Together, these 29 medications represent 10 protease inhibitors, 15 nucleoside reverse transcriptase inhibitors (NRTIs), three non-nucleoside reverse transcriptase inhibitors (NNRTIs), and one fusion inhibitor. ARV dosing recommendations and formulations are based on current U.S. Department of Health and Human Services (HHS) Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and from manufacturer product labeling information (specific formulations and dosing recommendations for pediatric use were not included in this analysis).

For each of the 29 ARVs, we examined formulary coverage, tier placement, out-of-pocket costs, and utilization management requirements by plan (Table 1). We compared the amount the 47 plans would charge enrollees for a 30-day supply (using the recommended dose) in the initial benefit period, in the coverage gap, and during the catastrophic coverage period (Table 2). We also profiled three individual case studies to illustrate the implications of our findings for people living with HIV/AIDS (Table 3). "Tom" and "Jeannette" receive the top two ARV regimens recommended by current HHS treatment guidelines, each of which consists of three ARVs.[16] Our third case, "Christopher", has been living with HIV for 20 years and has been on multiple HAART regimens over the course of his illness. His current drug regimen consists of four ARVs (two protease inhibitors and two NRTIs). He also takes an antidepressant, fluoxetine HCl (generic Prozac), and Lipitor to treat high cholesterol, a common side effect of some antiretroviral medications.

KEY FINDINGS

1. Do Medicare drug plans cover each of the antiretroviral medications approved by the FDA for people with HIV/AIDS?

All Medicare stand-alone PDPs cover each of the 29 drugs approved for the treatment of people with HIV/AIDS, consistent with CMS formulary guidelines. All 47 plans cover at least one formulation of the 10 protease inhibitors, 15 NRTIs, and three NNRTIs, and all cover the one available fusion inhibitor (Table 1).

For 2006, Medicare Part D plans are required to cover "all or substantially all" drugs in six specified classes, including antiretrovirals, according to formulary guidelines issued by CMS.[17] These classes represent categories of drugs in which lapses in treatment could cause significant negative outcomes in a short period of time for the beneficiary, and for which the diseases associated with these drugs have among the highest predicted drug and

medical costs. "Substantially all" means that all drugs in these categories are expected to be included in plan formularies, although exceptions are allowed as follows: for brand-name drugs with generic equivalents, plans must cover the brand-name and/or generic version; plans are not required to cover extended release versions of drugs where available (including weekly instead of daily doses); and plans are not required to cover all strengths and dosage forms, e.g., a drug available in both 100mg and 200mg strengths, or tablets, capsules, and liquid solutions of the same medication.

We find that the 47 PDPs in our analysis do not always cover brand-name drugs when a generic equivalent is available. For example, only 29 plans cover the brand-name drug Retrovir, while all 47 plans cover zidovudine, its generic equivalent. An even more important consideration for beneficiaries, however, could be whether Medicare Part D plans cover different formulations of a given drug. Some people, for example, may have difficulty swallowing and require an oral solution rather than a tablet. An individual who needs a specific formulation of a drug that is not covered by a Part D plan may be required to pay the full cost of the drug out of pocket. Costs for non-covered drugs or non-covered formulations would not apply toward the individual's benefit spending in order to qualify for catastrophic coverage. This could be an important consideration for enrollees with HIV/AIDS, though it was beyond the scope of our analysis to determine whether all formulations for each ARV were covered by the 47 plans.[18]

2. Is there variation in formulary tier placement of HIV/AIDS drugs across Medicare drug plans?

We found significant variation across Medicare drug plans in terms of tier placement of ARVs. Tier placement is important because it generally has a direct impact on enrollees' out-of-pocket costs.

Medicare drug plans have considerable flexibility in determining both the tier placement of prescription drugs that are included in their formulary and the out-of-pocket costs associated with each tier, provided the plan meets overall standards of actuarial equivalence relative to the legally-defined "standard" Part D drug benefit. (See text box below for description of the standard benefit.) In practice, most plans use a system of tiered cost-sharing amounts rather than a single coinsurance amount, as defined in the standard benefit. Typically, plans place groups of drugs together on different tiers, with escalating cost-sharing amounts for the beneficiary by tier.[19] Plans tend to place lower-cost generic drugs on the first tier, "preferred" brand-name drugs on the second tier, and "non-preferred" drugs on the third tier. Plans can use formulary tier placement of covered drugs to encourage enrollees to use generics instead of brand-name drugs, and preferred brands instead of non-preferred brands, with the aim of lowering costs to the plan as well as enrollees' out-of-pocket spending.

The standard drug benefit defined in the Medicare Modernization Act of 2003 (MMA) has a $250 deductible and 25% beneficiary coinsurance in the initial benefit period. The initial benefit period ends after $2,250 in total drug costs. From this point until catastrophic coverage begins (after a beneficiary incurs $3,600 in true out-of-pocket drug costs (TrOOP), which corresponds to $5,100 in total costs under the standard benefit), the beneficiary pays 100 percent of drug costs. This gap in coverage is commonly referred to as the "doughnut hole." Part D plan sponsor organizations must either offer at least one plan with the standard benefit design or a plan design that is actuarially equivalent to this benefit.

The 47 PDPs in Maryland varied in the decisions made with respect to tier placement of ARVs. As might be expected, the two available generic HIV/AIDS drugs are placed on Tier 1 by the majority of plans that cover them – 39 of 47 plans covering zidovudine and 39 of 44 plans covering didanosine. Most plans place the majority of HIV/AIDS drugs on

Tier 2, giving them preferred drug status (Table 1). However, placement of ARVs on Tier 3 or a specialty tier is not uncommon. For example, the majority of drug plans (29 of 47) place Agenerase, a protease inhibitor, on Tier 2, but 11 plans place it on Tier 3, and six plans put Agenerase on a specialty tier. Virtually all brand-name ARVs (26 of 27, all but Fuzeon) are placed on Tier 3 by nine or more of the PDPs. Two drugs – Aptivus, a protease inhibitor, and Videx EC, an NRTI – are on Tier 3 in at least as many plans as the number of plans where they are on Tier 2. Specialty tiers are generally reserved for some of the most expensive drugs, a plan feature that has substantial cost implications for enrollees (see Question 3 below).

The decision to place a drug on Tier 3 instead of Tier 2 could have major cost implications for beneficiaries who do not qualify for low-income financial assistance, since many plans require enrollees to pay at least twice as much for Tier 3 drugs than for Tier 2 drugs (Table 4). For example, the Sterling Prescription Drug Plan charges 25% for Tier 2 drugs and 50% for Tier 3 drugs, and the Medi-CareFirst Rx $250 Deductible Plan charges $18 for Tier 2 drugs and $40 for Tier 3 drugs.

3. Why does it matter to enrollees if plans place ARVs on a specialty tier?

The specialty tier merits attention because of its relatively high cost-sharing amount. The majority of PDPs in Maryland place at least one or more ARVs on a specialty tier.

Medicare drug plans are permitted to place certain "very high cost and unique" drugs, including antiretrovirals, on a "specialty" tier, with higher cost sharing than other formulary tiers. Drugs placed on a specialty tier are exempt from the normal rules governing the formulary exceptions and appeals processes.

A majority of all stand-alone prescription drug plans in Maryland use specialty tiers for one or more ARVs (32 of the 47 plans) and charge a copayment of between 25% and 33% of the drug's total cost. Of the 29 approved ARVs, 26 are on a specialty tier in at least one drug plan. A small number of PDPs use a specialty tier for a relatively large number of ARVs (Figure 1). For example, PacifiCare places 24 of 29 ARVs on a specialty tier (33% coinsurance) and AARP/United HealthCare places 14 of these drugs on a specialty tier (25% coinsurance).

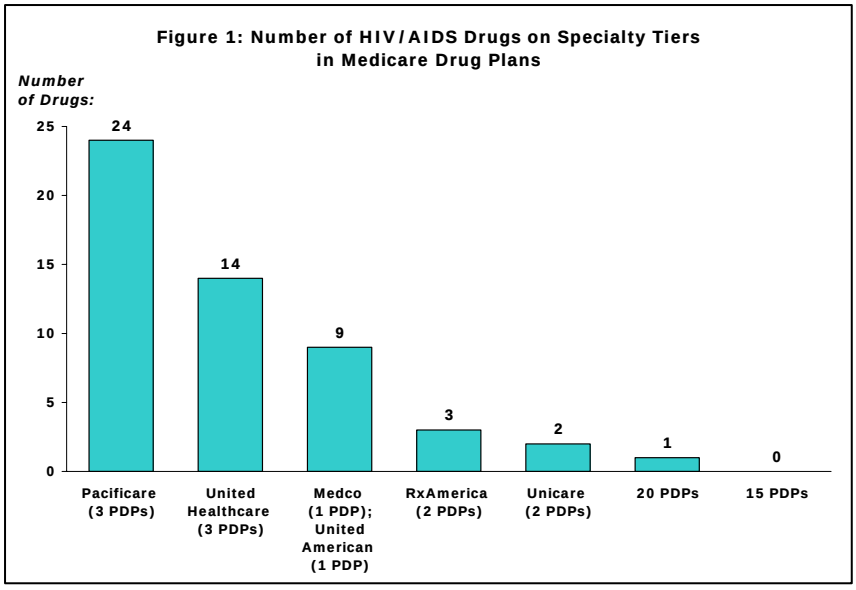


Figure 1: Number of HIV/AIDS Drugs on Specialty Tiers in Medicare Drug Plans

SOURCE: KFF analysis of data from Medicare Prescription Drug Plan Finder on Medicare.gov as of May 22, 2006.

Among the 32 PDPs that place ARVs on a specialty tier, 18 plans place only one drug, Fuzeon, on this tier. Fuzeon, administered via injection twice daily, is a relatively new ARV and is the only one in its class of ARV medications (fusion inhibitors). It is indicated for patients with HIV/AIDS who

are "treatment-experienced", meaning that prior ARV regimens have not worked effectively. Fuzeon is one of the most expensive HIV/AIDS drugs currently available, with an average negotiated price across the 47 plans in this analysis of $1,939 per month. Monthly cost sharing for Fuzeon when it is placed on a specialty tier can be as high as $650 per month in the initial benefit period and reaches almost $2,000 in the doughnut hole, when the enrollee is paying the full cost.

For a person with HIV/AIDS, a plan's decision to place a medication on a specialty tier can result in significantly higher out-of-pocket costs. For example, a PacifiCare Saver Plan enrollee who uses Combivir, which is on a specialty tier in this plan, would pay $111.31 per month – 33% of the total cost of $337.29 – during the initial benefit period. If instead the plan had placed Combivir on Tier 3, the enrollee would pay less than half of that amount, or $52.70 per month (Table 4).

The cost implications for enrollees can be illustrated by Christopher, one of the three individuals profiled for this report. Christopher takes two medications that United/AARP places on a specialty tier subject to a 25% coinsurance, Norvir and Reyataz. If Christopher enrolled in this plan, he would pay $67.96 per month for Norvir and $195.46 per month for Reyataz during the initial benefit period, for a total of $263 per month for these two drugs. If instead these drugs were on Tier 3, Christopher would pay less than half that amount for both drugs: $110 per month, or a copayment of $55 for each drug (Table 3).

4. Do Medicare drug plans typically impose utilization management restrictions, such as quantity limits, prior authorization, and step therapy, on HIV/AIDS drugs?

Utilization management restrictions are used infrequently by plans for HIV/AIDS drugs. In this way, plan formularies generally adhere to current formulary guidelines. In formulary guidance requiring coverage of all HIV/AIDS drugs, CMS stipulated that for patients already stabilized on these drugs before enrolling in a plan, "we generally expect that plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances."[20] In addition, CMS specified that for HIV/AIDS drugs "utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models." However, CMS did permit plans to use prior authorization for Fuzeon for new users.

Our analysis indicates that plans are more likely to use quantity limits than prior authorization requirements or step therapy restrictions. In fact, none of the 47 plans in Maryland uses step therapy for any of the 29 HIV/AIDS drugs. However, as many as seven plans impose quantity limits for Fuzeon, and each of the HIV/AIDS drugs are subject to quantity limits by one or more plan. Prior authorization requirements are not routinely applied to ARVs; however, 17 plans require prior authorization for Fuzeon, as permitted under CMS guidelines, and two plans require prior authorization for Aptivus and Crixivan, both protease inhibitors. Depending on how these utilization management tools are applied, they could pose significant challenges to obtaining ARVs for some people with HIV/AIDS.

5. What is the extent of variation in out-of-pocket costs for ARVs in the initial benefit period across Medicare drug plans?

For each of the 29 ARVs, there is considerable variation across plans in enrollees' out-of-pocket costs during the initial benefit period (Table 2). For example, an individual taking the recommended dose of Norvir, a protease inhibitor, would face cost-sharing amounts that range dramatically from a low of $15 to a high of $1,082.69 per month in the initial benefit period. A person taking the recommended dose of didanosine, a generic version of the NRTI Videx, would pay between $0 per month to $70.13 per month in the initial benefit period, depending on the drug plan he or she selected.

An important caveat is that beneficiaries who receive low-income subsidies under the Medicare drug benefit, including dual eligibles, are not subject to these costs or variations, since cost sharing for Part D plan enrollees with low-income subsidies is restricted by law. Individuals eligible for low-income subsidies would instead pay nominal copayments of up to $5 per month for each covered drug.

6. Are beneficiaries with HIV/AIDS likely to have spending in the so-called "doughnut hole" and, if so, how does this gap in coverage affect out-of-pocket spending?

Beneficiaries with HIV/AIDS are at risk for having significant expenditures in the so-called doughnut hole, unless they are low-income and qualify for additional financial assistance under the Medicare drug benefit. Under the law, PDPs are permitted to provide coverage in the doughnut hole; in Maryland, however, only six of the 47 plans offer any coverage in the doughnut hole, and only one of these plans (Humana PDP Complete) covers both generic and brand-name drugs in the doughnut hole.

As Table 2 shows, monthly costs for ARVs in the doughnut hole vary widely across PDPs, as they do in the initial benefit period. Given the high cost of many ARVs, people with HIV/AIDS taking ARVs can reach the doughnut hole within the first few months of coverage. How quickly enrollees reach the doughnut hole, how much they pay for drugs in the gap, and the number of months they pay the full cost for their drugs before they qualify for catastrophic coverage will depend on their total drug costs.

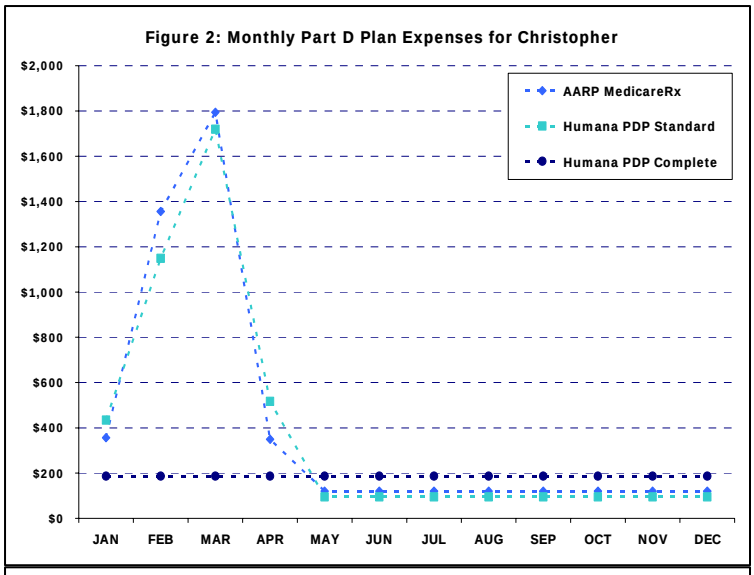
We calculated out-of-pocket expenses for Christopher, Tom, and Jeannette to see how long it would take for them to reach the doughnut hole, if they would have expenses in the doughnut hole, and whether they would ultimately qualify for catastrophic coverage. We compared their out-of-pocket spending in PDPs offered by the two companies that account for the largest share of Medicare PDP enrollment to date (United Healthcare and Humana).[21] We estimated their monthly costs under United's AARP MedicareRx Plan (which has the highest enrollment among United's three PDP products) and two of Humana's three PDPs: Humana PDP Complete, which covers brand-name and generic drugs in the doughnut hole, and Humana PDP Standard, which has no coverage in doughnut hole, but is typically the lowest-premium plan in regions where Humana plans are offered. Based on our comparison of these three plans, we find:

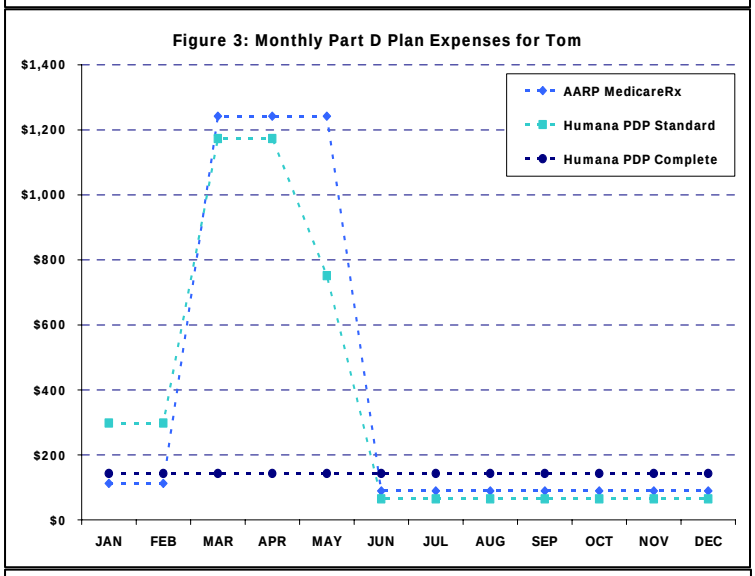
- People with HIV/AIDS who take ARVs are highly likely to have expenditures in the doughnut hole, unless they are receiving low-income subsidies. All three of our case study individuals would reach the doughnut hole within two or three months of enrolling in a PDP, assuming they do not enroll in a plan that provides coverage in the gap (Figures 2, 3, and 4).

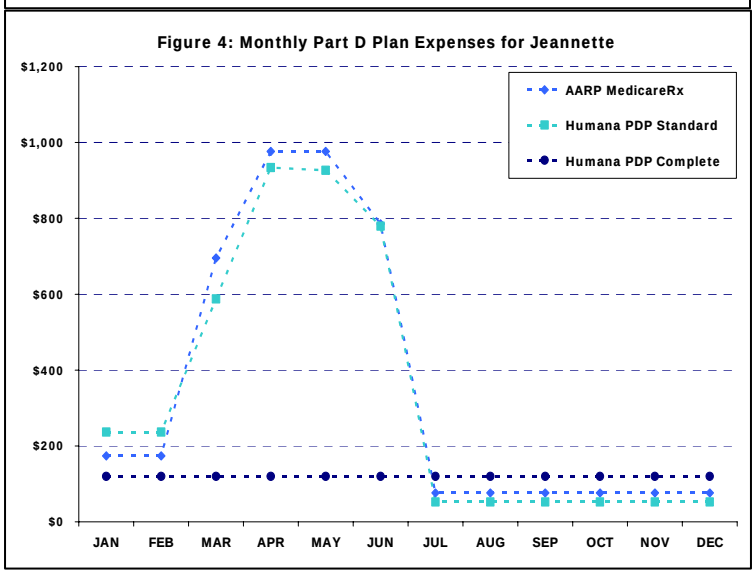
- Those who reach the doughnut hole are likely to experience a significant increase in their monthly out-of–pocket drug costs. Christopher's monthly expenses, for example, would quadruple under Humana PDP Standard and increase five-fold under the AARP MedicareRx Plan.

- Beneficiaries with HIV/AIDS are likely to have expenditures in the doughnut hole for several months. Christopher and Tom would have expenses in the doughnut hole for three months, and Jeanette would have expenses in the doughnut hole for four months.

- Enrollees who take ARVs are likely to qualify for catastrophic coverage due to the high cost of their medications. All three of our case studies would have catastrophic coverage under their Medicare drug plan for at least five months of the year.







Notes to Figures 2-4: Monthly expenses include out-of-pocket drug costs and Part D plan premiums.
SOURCE: KFF analysis of data from Medicare Prescription Drug Plan Finder on Medicare.gov as of May 22, 2006.

7. Are costs likely to be a concern for people with HIV/AIDS once they reach the catastrophic coverage period?

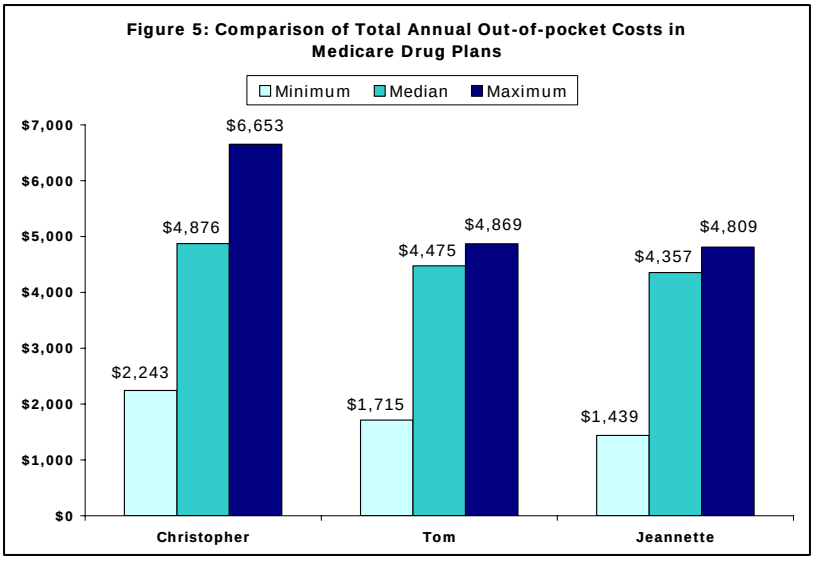
Although the defined standard benefit in the MMA limits cost sharing to 5% of the total cost of a drug during the catastrophic coverage period, people with HIV/AIDS should still anticipate and budget for medication costs once they reach the point at which the plan covers 95% of costs. Under the three plans we examined for our case studies, Christopher would pay between $91 and $134 per month for out-of-pocket drug costs alone (that is, excluding Part D plan premiums for the three plans). Tom would pay between $60 and $90 per month for drug costs, while Jeanette would pay between $47 and $67 per month for her drugs, also excluding premiums.

Our analysis also shows that there is some variation among PDPs in the amount an enrollee would pay for covered drugs in the catastrophic coverage period (Table 2). This variation exists because each plan negotiates separately with drug companies to determine the prices they will charge for each drug. These prices are used as the basis to determine the beneficiary's cost-sharing amount, and some plans negotiated lower total drug prices than others. In most cases the variation is minimal, but for some drugs, the difference is quite substantial.

8. Does the choice of Medicare drug plan really matter for people with HIV/AIDS, since plans are required to cover all antiretroviral drugs?

Because plans charge different amounts for drugs in the initial benefit period, the doughnut hole, and even during the catastrophic coverage period, the total annual cost to an individual to enroll in a PDP and fill their prescriptions varies widely across plans.

The variation in total annual cost across plans can have significant cost implications for individuals, as our case studies illustrate (Figure 5). Christopher would pay between $2,243 and $6,653 per year out-of-pocket for his six medications, along with plan premiums and deductibles (where applicable). He would reach the doughnut hole in all 47 plans and would reach the catastrophic coverage level in all plans with the exception of Humana PDP Complete. For Tom, assuming he has no other drug costs and uses an in-network pharmacy, his estimated annual costs would range from $1,715 to $4,869. He would also reach the catastrophic coverage level in all available plans except for Humana PDP Complete. Jeannette's estimated annual costs would range from



SOURCE: KFF analysis of data from Medicare Prescription Drug Plan Finder on Medicare.gov as of May 22, 2006.

$1,439 to $4,809. As with Christopher and Tom, Jeanette would reach the catastrophic coverage level in all available plans with the exception of Humana PDP Complete.

Although some beneficiaries may be attracted to plans with low premiums, they may face lower total annual costs by enrolling in a higher-premium plan. We find that all three individuals would pay more over the course of 12 months under Humana's lowest-premium plan (Humana PDP Standard) than in Humana's highest-premium plan that offers coverage in the doughnut hole (Humana PDP Complete).

9. How long does it take newly approved pharmaceuticals to be covered by Medicare Part D plans?

At the time of this analysis, the answer is unknown. Since June 2006, one new antiretroviral drug and a new, fixed-dose combination regimen of three previously approved ARVs have been approved by the FDA. Prezista (darunavir), a new protease inhibitor, was approved for use on June 23, 2006.[22] Prezista is indicated for people with HIV who have not responded to treatment with existing ARVs, and is therefore an important new option for some. Atripla, approved on July 12, 2006, is the first fixed-dose combination of three widely-used antiretroviral drugs in a single tablet, to be taken once a day.[23] This new treatment offers a significantly simplified treatment regimen that can improve patient adherence and therefore reduce the risk of viral resistance.

As of July 18, Prezista was not listed on the online Medicare Formulary Finder (we did not expect Atripla to be listed because it only became available for purchase in the U.S. as of July 16). To verify whether Part D plans had made coverage decisions with regard to this new treatment, we called the five companies with the largest Part D enrollment to assess whether or not Prezista was available. Representatives from four companies (United Healthcare, Humana, Memberhealth, and WellCare) reported that Prezista was not on their formularies. The fifth company (Wellpoint) did have Prezista on Tier 2 of its formulary, subject to prior authorization requirements.

CONCLUSION

The findings of this study have several important implications for Medicare beneficiaries with HIV/AIDS, and highlight the complexities they face when choosing among available Part D plans. Ultimately, we find that plan choice matters. Specifically, our analysis indicates the following:

- First, and perhaps most importantly, our analysis confirms that all Part D plans in this study cover all FDA-approved antiretrovirals, consistent with CMS formulary guidelines. Part D, therefore, offers an important new option for people with HIV/AIDS for obtaining their medications.
- Although all plans cover all FDA-approved ARVs, they do not necessarily cover all formulations of each ARV, which could pose challenges for beneficiaries. Some plans do not cover both brand and generic medications where generics are available.
- In addition, despite this broad coverage, there is considerable variation by plan across several key dimensions, including tier placement, cost-sharing arrangements, and the amounts plans charge beneficiaries in the initial benefit period, the doughnut hole, and even during the catastrophic coverage period. Each of these factors alone has cost

implications for beneficiaries and, together, they may present significant costs, depending on which plan beneficiaries choose and how many medications they take:

  - Specialty tiers, generally reserved for some of the most expensive drugs and a tier placement that typically involves relatively high cost sharing for enrollees, are used by most plans for at least one ARV.
  - Cost-sharing differences across plans are extreme, as illustrated by the case studies. Tom faces a five-fold difference between the lowest and highest-cost plan. Christopher could see a 16-fold difference in the monthly cost of one of his drugs, Reyataz, in the initial benefit period and a 27-fold difference in the doughnut hole across plans.

- The doughnut hole should be an important consideration for people with HIV/AIDS, given the high costs of ARVs. Our findings suggest that those without supplemental assistance are likely to reach the doughnut hole relatively quickly, and are likely to pay the full cost of their medications in the doughnut hole for several months before qualifying for catastrophic coverage.
- Beneficiaries who reach the doughnut hole are likely to qualify for the catastrophic benefit, and when they do, are likely to see a substantial reduction in their monthly expenses.
- Even if beneficiaries with HIV/AIDS are careful to choose a plan that is most likely to meet their needs at the start of the year, they may face unpredictable costs over the course of the year. People with HIV/AIDS are often faced with the need to change their ARV therapy and may find that the plan they originally selected may not be their best option going forward. Indeed, a change in treatment regimen could place the drugs out of financial reach if, for example, the new drug needed is subject to higher cost sharing or placed on a specialty tier.

There are also considerations for beneficiaries with HIV/AIDS beyond ARV coverage. For those who rely on non-ARV medications, many of which are quite important in the context of HIV care, they may find that the plan that offers the best coverage for their ARVs may not provide the best coverage for their other medications.

The findings of this report also have important implications for low-income beneficiaries who are dually eligible for Medicaid and Medicare and were auto-assigned to a Medicare drug plan as of January 1, 2006. It would appear that those who are dually eligible for Medicare and Medicaid have access to the full range of FDA-approved ARVs under the PDPs to which they were assigned. However, the cost of filling prescriptions may be a concern particularly for individuals who were not paying copayments for their ARVs under Medicaid, and who are now required to pay up to $5 for each of their medications.

Finally, there are implications for other programs that serve people with HIV/AIDS, particularly the AIDS Drug Assistance Program (ADAP). ADAP payments for medications cannot be applied toward a beneficiary's true out-of-pocket costs (TrOOP), which are used to determine when a beneficiary qualifies for catastrophic coverage. Many ADAP programs will pay Part D co-payments and help beneficiaries with expenses in the doughnut hole.[24] Because ADAP payments do not count toward the TrOOP, enrollees who benefit from ADAP payments are less likely to qualify for catastrophic benefits. As a result, ADAP programs that supplement Part D in this manner will continue to make payments on behalf of enrollees for the remainder of the year because the enrollee is unlikely to meet the Medicare plan's catastrophic threshold. Given the high cost of ARVs and the high likelihood that

beneficiaries with HIV/AIDS will reach the doughnut hole, ADAPs are likely to face sustained cost pressures.

Medicare Part D is an important step forward in drug coverage for beneficiaries with HIV/AIDS. However, as this analysis demonstrates, Part D is not without challenges, and plan choice does matter. As such, there are important lessons not just for beneficiaries with HIV/AIDS, but for all Medicare beneficiaries with multiple, high-cost drug needs. As beneficiaries with HIV/AIDS make plan decisions, they will weigh multiple tradeoffs related to costs and coverage, doing their best to choose a plan based on information available to them at the time. Given the vulnerabilities of this population, the complexities of HIV disease and ARV therapy, and the critical role drugs play in the treatment of HIV, it will be important to monitor how the new Medicare drug plans are working for beneficiaries with HIV/AIDS and assess their access to medications over time.

NOTES

[1] Kaiser Family Foundation analysis of data from the White House Office of Management and Budget, Congressional Appropriations bills, HHS Office of Budget, Centers for Medicare and Medicaid Services, and Congressional Research Service. Medicare spending data represent estimates provided by CMS.
[2] Sources: Bozzette S., et al. "The Care of HIV-Infected Adults in the United States." *NEJM*, Vol. 339, No. 26, December 1998; Kaiser Family Foundation, *Fact Sheet: Medicare and HIV/AIDS*, September 2005. This estimate is from the HIV Cost and Services Utilization Study (HCSUS), the only nationally representative study of people with HIV/AIDS in care. However, data are from 1996 and therefore may not represent the current profile of this population.
[3] Medicare replaces Medicaid as the primary source of drug coverage for low-income and disabled people with both Medicare and Medicaid ("dual eligibles"). Enrollment in Medicare drug plans is voluntary for most beneficiaries, with the exception of dual eligibles and certain low-income beneficiaries who are automatically enrolled in a drug plan if they do not choose one on their own.
[4] NCHS, "Data Warehouse, Death rates by 10 -year age group and age-adjusted death rates for 113 selected causes, race and sex: United States, 1979-1998 (Table HIST001R)".
[5] NCHS, "Deaths: Preliminary Data for 2003", *NVSR*, Vol. 53, No. 15.
[6] Studies have shown that people with HIV/AIDS who have been on ARV treatment for several years may have used as many as 10 or more different ARVs, including drugs in multiple ARV classes. See references 197, 206-207, 210-212, 223-225 in HHS, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," May 2006 (available at: aidsinfo.nih.gov/Guidelines).
[7] There are three kinds of measures of "failure" in the context of ARV therapy: virologic failure, immunologic failure, and clinical failure.
[8] Based on average wholesale price (AWP) data from 2005. Most purchasers pay below AWP for medications.
[9] Kaiser Family Foundation, *Financing HIV/AIDS Care: A Quilt with Many Holes*, May 2004.
[10] More than half (approximately 65,000) of all Medicare beneficiaries with HIV/AIDS are estimated to be dually eligible for Medicaid; these low-income beneficiaries were automatically enrolled in the new prescription drug benefit as required under the MMA. See: Kaiser Family Foundation, *Fact Sheet: Medicare and HIV/AIDS*, September 2005.
[11] In June 2005, 13% of clients served by ADAPs were Medicare beneficiaries. See: Kaiser Family Foundation, *National ADAP Monitoring Report, Annual Report 2006*, March 2006.
[12] There are 48 plans offered in Maryland, but we omitted one (ElderHealth PDP Mid-Atlantic) from the analysis due to constraints in the data that were publicly available regarding this plan's formulary and costs. The analysis also does not include coverage under Medicare Advantage plans. Of the 47 plans in this study, premiums range from $6.44 to $68.91; of the 20 plans that charge a deductible, 17 have a $250 deductible and 3 charge $100.
[13] Our analysis does not explicitly compare differences between Medicare drug plans that are available to people receiving low-income subsidies with other plans. Because beneficiaries who receive low-income subsidies are entitled to full or reduced premium subsidies and pay nominal copayments, the key concerns relate more to coverage and cost management restrictions rather than out-of-pockets costs.
[14] Three of these drugs have been or will be discontinued: Hivid, Videx buffered tab, and Fortovase. See: HHS, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," May 2006 (available at: aidsinfo.nih.gov/Guidelines).
[15] Sources: HHS, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," May 2006 (available at: aidsinfo.nih.gov/Guidelines); and HHS, Food and Drug Administration, "Drugs Used in the Treatment of HIV Infection," October 2005 (available at: www.fda.gov/oashi/aids/virals.html).
[16] Source: HHS, Guidelines for the Use of Antiretroviral Agents in *HIV-Infected Adults and Adolescents*, May 2006, Table 6 (available at: aidsinfo.nih.gov/Guidelines). The top two recommended regimens are those specified for treatment-naïve patients.
[17] Formulary guidelines issued by CMS in 2005 were based on a therapeutic classification scheme developed specifically for Medicare drug plans by the United States Pharmacopoeia (USP). These guidelines require a minimum number of drugs to be covered in each class and key drug type of the USP classification system, and coverage of all or substantially all drugs in six specified classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immune suppressants).
[18] One example is Emtriva, an NRTI, which comes in both capsule and liquid solution, but the Plan Finder does not show whether solutions are covered.
[19] In a separate analysis, researchers found that among PDPs with three tiers, median cost sharing for Tier 2 drugs was five times the median cost-sharing amount for Tier 1 drugs ($25 vs. $5 for a 30-day supply). The median cost-sharing amount for Tier 3 drugs ($53 for a 30-day supply) was more than twice that of Tier 2 drugs. See *An In-Depth Examination of Formularies and Other Features of Medicare Drug Plans*, Kaiser Family Foundation, April 2006, www.kff.org/medicare/7489.cfm.
[20] See CMS, "Clarification Formulary Review – 'All or Substantially All'" (available at: www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidanceAllorSubAll.pdf).
[21] Part D enrollment data are available at: www.cms.hhs.gov/PrescriptionDrugCovGenIn/02_EnrollmentData.asp#TopOfPage. See "Top PDP Plans by Number Enrolled (v04.27.06).
[22] FDA, "FDA Approves New HIV Treatment for Patients Who Do Not Respond to Existing Drugs", June 23, 2006 (available at: www.fda.gov/bbs/topics/NEWS/2006/NEW01395.html).
[23] FDA, "FDA Approves the First Once-a-Day Three-Drug Combination Tablet for Treatment of HIV-1", July 12, 2006 (available at: www.fda.gov/bbs/topics/NEWS/2006/NEW01408.html).
[24] Kaiser Family Foundation, *National ADAP Monitoring Report, Annual Report 2006*, March 2006.

Table 1: Coverage of HIV/AIDS Drugs by Medicare Drug Plans

Name of drug	Number of plans covering drug	Formulary tier placement				Utilization management tools		
		Tier 1	Tier 2	Tier 3	Specialty Tier	Quantity limits	Prior authori-zation	Step therapy
Protease Inhibitors								
Agenerase	47	1	29	11	6	2	--	--
Aptivus	47	1	19	19	8	4	2	--
Crixivan	47	1	27	11	8	4	2	--
Fortovase[1]	47	1	34	9	3	2	--	--
Invirase	47	1	28	10	8	2	--	--
Kaletra	47	1	31	10	5	2	--	--
Lexiva	47	1	30	10	6	2	--	--
Norvir	47	1	28	10	8	2	--	--
Reyataz	47	1	30	10	6	4	--	--
Viracept	47	1	27	11	8	2	--	--
NRTIs								
Combivir	47	1	28	12	6	2	--	--
Emtriva	47	1	31	12	3	5	--	--
Epivir	47	1	34	12	--	2	--	--
Hivid[1]	47	1	30	13	3	2	--	--
Retrovir	29	1	17	10	1	2	--	--
Zidovudine[2]	47	39	4	--	4	1	--	--
Trizivir	47	1	28	12	6	2	--	--
Videx[1]	47	1	30	13	3	2	--	--
Videx EC	35	1	16	17	1	2	--	--
Didanosine[2]	44	39	2	--	3	1	--	--
Viread	47	1	29	12	5	2	--	--
Zerit	47	1	34	12	--	2	--	--
Ziagen	47	1	34	12	--	2	--	--
Epzicom	47	1	28	12	6	2	--	--
Truvada	47	1	27	13	6	2	--	--
Fusion Inhibitors								
Fuzeon	47	1	14	2	30	7	17	--
NNRTIs								
Rescriptor	47	1	31	12	3	2	--	--
Sustiva	47	1	31	12	3	2	--	--
Viramune	47	1	28	13	5	2	--	--

Note: [1] Indicates drug that is being discontinued. [2] Zidovudine is the generic form of Retrovir and Didanosine is the generic form of Videx.
SOURCE: KFF analysis of data from Medicare Prescription Drug Plan Finder on Medicare.gov as of May 22, 2006.

Table 2: Monthly Cost Sharing for HIV/AIDS Drugs in Medicare Drug Plans, by Benefit Level

	Recommended monthly amount		Estimated monthly out-of-pocket costs					
			Initial benefit period		Doughnut hole		Catastrophic coverage	
Name of drug	Dosage	Quantity	Low	High	Low	High	Low	High
Protease Inhibitors								
Agenerase	84000 mg per month		$15.00	$277.55	$30.00	$856.62	$5.00	$42.83
Aptivus	250 mg	120	$18.00	$314.12	$60.00	$1,007.76	$46.97	$50.39
Crixivan	400 mg	180	$15.00	$160.81	$60.00	$493.09	$11.95	$24.65
Fortovase[1]	200 mg	540	$15.00	$220.95	$30.00	$681.43	$5.00	$34.07
Invirase	500 mg	120	$15.00	$210.61	$30.00	$645.72	$19.05	$32.29
Kaletra	Tablet	120	$15.00	$149.56	$30.00	$458.52	$5.00	$22.93
Lexiva	700 mg	60	$15.00	$194.41	$30.00	$599.56	$5.00	$29.98
Norvir	100 mg	360	$15.00	$1,082.69	$30.00	$3,280.99	$156.85	$164.05
Reyataz	200 mg	60	$15.00	$249.65	$30.00	$800.62	$14.84	$40.03
Viracept	625 mg	180	$15.00	$319.02	$30.00	$978.10	$47.71	$48.91
NRTIs								
Combivir	Tablet	60	$15.00	$221.95	$30.00	$684.48	$31.29	$34.22
Emtriva	400 mg	30	$15.00	$79.19	$30.00	$316.76	$14.77	$15.84
Epivir	200 mg	30	$15.00	$79.19	$30.00	$316.76	$14.48	$15.84
Epzicom	150 mg	60	$15.00	$239.85	$30.00	$739.72	$33.85	$36.99
Hivid[1]	Tablet	30	$15.00	$66.00	$30.00	$222.15	$10.79	$11.11
Retrovir	300 mg	60	$15.00	$92.45	$30.00	$369.78	$18.00	$18.49
Zidivudine[2]	20 ml vial	90	$0.00	$78.98	$2.00	$315.93	$2.00	$15.80
Trizivir	Tablet	60	$15.00	$359.09	$30.00	$1,107.44	$50.62	$55.37
Truvada	Tablet	30	$15.00	$242.70	$30.00	$792.51	$36.77	$39.63
Videx[1]	200 mg	60	$15.00	$66.46	$30.00	$276.86	$12.52	$13.84
Videx EC	400 mg	30	$15.00	$77.88	$30.00	$311.50	$14.68	$15.58
Didanosine[2]	300 mg	30	$0.00	$70.13	$2.00	$280.53	$11.22	$14.03
Viread	40 mg	60	$15.00	$155.83	$30.00	$477.75	$22.11	$23.89
Zerit	300 mg	60	$15.00	$86.78	$30.00	$347.13	$16.35	$17.36
Ziagen	300 mg	60	$15.00	$106.24	$30.00	$424.96	$19.43	$21.25
Fusion Inhibitors								
Fuzeon	Kit	1	$18.00	$650.13	$492.40	$1,993.24	$97.29	$99.66
NNRTIs								
Rescriptor	200 mg	180	$15.00	$68.51	$30.00	$274.05	$13.32	$13.70
Sustiva	600 mg	30	$15.00	$139.93	$30.00	$448.68	$21.14	$22.43
Viramune	200 mg	60	$15.00	$130.35	$30.00	$399.63	$19.46	$19.98

Note: [1] Indicates drug that is being discontinued. [2] Zidovudine is the generic form of Retrovir and Didanosine is the generic form of Videx.
SOURCE: KFF analysis of data from Medicare Prescription Drug Plan Finder on Medicare.gov as of May 22, 2006.

Table 3: Case Study Prescription Drug Regimens and Cost Sharing in Medicare Drug Plans

	Drug name	Dosage	Quantity per month	Initial benefit period	Doughnut hole[1]	Catastrophic coverage[1]
				Low - High	Low - High	Low - High
Monthly drug regimen for Christopher	Didanosine[2]	250 mg	30	$0 - $65.30	$2 - $180.33	$7.22 - $9.02
	Norvir	100 mg	30	$15 - $90.83	$30 - $278.47	$13.54 - $13.92
	Reyataz	150 mg	60	$15 - $249.65	$30 - $800.62	$37.71 - $40.03
	Viread	300 mg	30	$15 - $155.83	$30 - $477.75	$22.11 - $23.89
	Fluoxetine HCl[2]	20 mg	30	$0 - $10	$2 - $87.29	$0.31 - $4.36
	Lipitor	10 mg	30	$17 - $66	$30 - $78.91	$3.77 - $5
NNRTI-based monthly drug regimen for Tom[3]	Emtriva	200 mg	30	$15 - $78	$295 - $313	$15 - $16
	Sustiva	600 mg	30	$15 - $140	$423 - $449	$21 - $22
	Viread	300 mg	30	$15 - $156	$271 - $472	$22 - $23
Protease inhibitor-based monthly drug regimen for Jeannette[3]	Epivir	300 mg	30	$15 - $80	$30 - $317	$14 - $16
	Kaletra	200-50 mg	120	$15 - $150	$447 - $663	$22 - $33
	Zidovudine	300 mg	60	$0 - $79	$2 - $316	$2 - $16

Note: [1] Not including Humana PDP Complete, which has no doughnut hole. [2] Generic drugs.
[3] Drug regimens based on HHS recommendations.
SOURCE: KFF analysis of data from Medicare Prescription Drug Plan Finder on Medicare.gov as of May 22, 2006.

Table 4: Cost Sharing by Formulary Tier for Lowest-Premium Medicare Drug Plans in Maryland

Name of PDP sponsor	Name of PDP	Cost-sharing amount			
		Tier 1	Tier 2	Tier 3	Specialty tier
Aetna Medicare	Aetna MedicareRx Essentials	$5	$25	--	--
AmeriHealth Advantage	AmeriHealth Advantage Rx Option 1	25%	--	--	--
CIGNA HealthCare	CIGNATURE Rx Value	$4	$20	$40	--
Coventry AdvantraRx	AdvantraRx Value	$10	$42	--	--
First Health Premier	First Health Premier	25%	25%	25%	25%
Humana Inc.	Humana PDP Standard	25%	25%	25%	25%
Medco Health Solutions, Inc.	YOURx Plan	$4	$17	75%	25%
Medi-CareFirst	Medi-CareFirst Rx $250 Deductible Plan	$5	$18	$40	25%
MEMBERHEALTH	Community Care Rx Basic	$0	25%	45%	--
Pacificare Life and Health Insurance Co.	Pacificare Saver Plan	$7.50	$22	$52.70	33%
Pennsylvania Life Insurance Co.	Prescription Pathway Bronze	25%	25%	25%	--
RxAmerica	Advantage Star Plan	$2	25%	25%	25%
SilverScript	SilverScript	$9	25%	--	25%
Sterling Prescription Drug Plan	Sterling Prescription Drug Plan	$10	25%	50%	25%
Unicare	MedicareRx Rewards	$5	$25	25%	25%
United American Insurance Co.	UA Medicare Part D Prescription Drug Cov	$9	$30	$60	33%
United Healthcare	AARP MedicareRx Plan	$5	$28	$55	25%
United Healthcare	United Medicare MedAdvance	$10	$23	$53	25%
WellCare	WellCare Signature	$0	$66	--	31%

Note: List excludes Elder Health PDP Mid Atlantic because of problems in data collection for this plan. '--' indicates not applicable.
SOURCE: CMS, Landscape of Plan Options in Maryland; plans approved as of 11/13/05.

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