Prepared by InterGroup Services, Inc. for the
Greater Baltimore HIV Health Services Planning Council

Medicare Part D: Baltimore EMA Impact Assessment

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1. EXECUTIVE SUMMARY

The research and analysis presented in this report was performed by InterGroup Services, Inc. (IGS), a Baltimore-based consulting and project-management company, on behalf of the Greater Baltimore HIV Health Services Planning Council. The planning council is responsible for planning and prioritizing the need for funds received by the Baltimore eligible metropolitan area (EMA) under Title I of the Ryan White CARE Act (RWCA), which provides emergency funds for health and supportive services for people living with HIV/AIDS (PLWH/As).

The planning council commissioned this report in the wake of a new federal prescription drug program that went into effect on January 1, 2006 as a result of the 2003 Medicare Modernization and Improvement Act (MMA). On that date, anyone qualified for the federal Medicare program — primarily senior citizens — became eligible to enroll in one of dozens of Medicare Part D prescription drug plans (PDPs) available in most states. On that same date, individuals who qualified for the state- and federally funded Medicaid program — primarily the poor disabled — as well as Medicare were to have been automatically enrolled in one of the new Part D PDPs.

The planning council, concerned about the impact of the new Part D program on individuals eligible for both Medicare and Medicaid (known as "dual eligibles" or "DEs"), and thus on the Ryan White CARE Act funds it is responsible for planning, sought to determine the number of dual eligibles in the Baltimore EMA as well as what new costs, if any, those DEs might incur under Part D.

1.1 Medicare Part D in Maryland

As research progressed, it became clear that there were some important distinctions to be made about the ways in which Part D beneficiaries might experience undesirable consequences under the new program, and that there could be no short answers to the planning council's questions. The reason for both is the extreme flexibility that the U.S. Centers for Medicare and Medicaid Services (CMS) allows PDPs in structuring their drug coverage and cost sharing.

If it were the case that PDPs were required to offer a standard, uniform benefit, approving prescriptions on demand (or on a physician's prescription), as Maryland Medicaid did prior to January 1, 2006, it would be possible to unequivocally state the following: Maryland's dual eligibles will experience almost no changes in the cost of their prescription coverage, while those with slightly higher incomes will experience a significant improvement in their ability to pay for drugs.

Since it is not the case that PDPs are required to offer a standard, uniform benefit, considerable uncertainty exists as to the precise effects of Part D on individual beneficiaries. Evaluation of the extent to which Maryland beneficiaries, DE or not, might experience difficulties obtaining prescribed drugs would require detailed comparisons of the over 40 PDPs approved for use in Maryland; this analysis was not performed as it was outside the scope of the planning council's research request. For that reason, it is important to remember that much of the analysis in this report operates under the assumptions that Part D beneficiaries will:

- Receive the medications prescribed to them by their physicians on demand, and
- Pay only the precise copay and other cost-sharing amounts implied by CMS's model benefit.

Neither of these assumptions may hold for a given PDP; to the extent that these assumptions do not hold, the analysis in this report may not accurately represent the individual costs likely to be incurred by Part D beneficiaries.

Also figuring heavily in this report's analysis is the fact that two Maryland agencies have announced that they will subsidize costs incurred under Part D by beneficiaries with incomes less than 500 percent of the federal poverty level (FPL). The Maryland AIDS Drug Assistance Program (MADAP) and the Senior Prescription Drug Program (SPDAP) will essentially eliminate all premium, deductible and copay costs for all Part D beneficiaries with incomes under 500 percent FPL.[1] As a result, more Marylanders than ever before will enjoy low- or no-cost access to their prescription drugs.

Given the assumptions stated above, it is possible to make several broad statements about the effects of Part D (based on CMS's model benefit):

- Part D is only a minor change for DEs; because of the "extra help" subsidy, Part D offers a benefit that is not any more expensive than Medicaid's drug benefit was.
- Part D is a significant improvement for slightly higher-income Marylanders; before Part D, these would only have been eligible for help with their drugs from the Maryland Pharmacy Discount Program (MPDP), which required much higher copays than does the Part D model benefit.
- Part D offers a drug benefit for other non-DEs who never before had access to a particularly robust public drug benefit.

As noted above, these positive-sounding conclusions may not reflect every beneficiary's experience in every PDP, because of (1) problems inherent to the Medicare Modernization Act as written and (2) a significant number of technical glitches, missteps and non-compliance with regulations that have attended the Part D program's rollout.

Problems inherent to the program as designed include the PDPs' great flexibility in deciding which drugs to cover and how to structure cost sharing; potentially arduous exceptions and appeals processes; and elastic use of the term "covered drugs."

Implementation glitches include dissemination of inaccurate coverage and cost information by both CMS and individual PDPs; CMS's failure to properly process and handle the records of hundreds of thousands of enrollees, resulting in denial of coverage and extra help subsidies; inadequate preparation for high volumes of traffic on CMS and PDP computer and helpline systems, resulting in system crashes and inordinately long hold times for pharmacists verifying enrollment information; and non-compliance by most PDPs with CMS's directive that they publicize their plans for avoiding interruptions in the existing drug regimens of new enrollees ("transition plans"). Also, drug manufacturers were recently warned by the inspector general of the U.S. Department of Health and Human Services (HHS) that their programs offering free medications to low-income clients may violate federal anti-kickback laws; as a result, most manufacturers are discontinuing these programs.

In addition, initial enrollment has been lower than expected, and there is reason to suspect that it is the sickest, poorest Medicare eligibles who are most likely to sign up for the program. If this continues to be the case, it is possible that some companies will lose interest in sponsoring Part D

[1] Though the program's name implies that it is for senior citizens only, there are only income — not age — restrictions on SPDAP eligibility.

PDPs, while others may shrink their formularies and increase cost sharing, with negative effects on lower-income beneficiaries.

Medicare Part D, then, represents a massive change in the structure of health-care delivery in this country and in the state of Maryland. While the poorest beneficiaries seem relatively well protected from the worst of the potential problems inherent to the benefit, the bungled rollout does not bode well for the continued health of the program and indicates a need for continued close monitoring.

1.2 Planning Implications

It remains uncertain how the Medicare Part D prescription-drug benefit will affect each individual enrollee and, as a result, how it will affect PLWH/As' access to care in the Baltimore EMA. If it were the case that all Part D enrollees could easily obtain all prescribed medications (as would essentially have been the case for Maryland DEs prior to Part D, through Medicaid), then it would be safe to say that the nearly 1,000 HIV-positive DEs in the Baltimore EMA will not be much affected by the change at all. There is, however, reason to doubt that all Part D beneficiaries will be able to easily obtain all prescribed medications, although a precise determination of the extent of such problems would require a case-by-case, PDP-by-PDP analysis — an analysis vastly more complex that that requested by the planning council.

Despite the uncertainty, it is possible to offer three specific courses of action that the planning council should take: (1) establishing MADAP as a fundable category so that emergency funds can be made available to the state should it need help subsidizing Part D benefits for EMA PLWH/As, (2) prohibiting providers from paying any Part D costs, instead allowing those costs to be subsidized through MADAP, and (3), opening and maintaining formal communication with MADAP so that the council is aware as early as possible of any emerging need for fund reallocations.

It is important to note that the Medicare Part D program remains a work in progress. For example, on February 24, 2006, CMS publicly requested recommendations to improve Part D (Frekin 2006), and various members of Congress have expressed their desire to amend the MMA. Readers are therefore cautioned to double-check all technical details of Part D mentioned in this report, which — except as noted otherwise — may be considered current as of early February 2006.

2. INTRODUCTION

Medicare Part D is an optional, outpatient prescription-drug benefit offered through the federal Medicare program, which is administered by CMS, an arm of HHS. Medicare benefits are available to the elderly and disabled. Starting on January 1, 2006, anyone qualified for Medicare was eligible to enroll in one of the dozens of Part D PDPs available in most states.

Part D is often discussed in terms of its effects on senior citizens, who constitute the majority of Medicare beneficiaries. However, Part D also affects the disabled and, in particular, the poor disabled, such as those who qualify not only for Medicare but also Medicaid, the state- and federally funded system of health-care benefits for those earning particularly low incomes. These beneficiaries, known as "dual eligibles," previously received comprehensive prescription-drug coverage through Medicaid, but, as of January 1, 2006, DEs lost their eligibility for the Medicaid prescription-drug benefit and were to have been automatically enrolled in one of the new Part D PDPs.

One entity with an interest in the effects of this change is the Greater Baltimore HIV Health Services Planning Council, also known as the planning council. The planning council is a mayorally appointed body responsible for prioritizing the annual expenditure of some $20 million in federal funds for health and supportive services for PLWH/As in Baltimore City and six surrounding counties, a region referred to as the EMA. These funds are made available through Title I of the Ryan White CARE Act. Realizing that the advent of Medicare Part D would bring drastic changes for DEs, and concerned about reports that Part D would bring higher copays and greater coverage gaps than existed under Medicaid, the planning council wondered about the possible financial effects of the switch on dually eligible PLWH/As. Specifically, the council was concerned that the changes brought about by Part D might cause dually eligible PLWH/As to become clients of services funded under Title I of the CARE Act, thus constituting an additional strain on Title I funds that would have to be planned for accordingly. To investigate this possibility, the planning council commissioned this report from its support office, InterGroup Services, Inc.

The planning council's two main questions, intended to determine the effect of the switch to Part D on the EMA's continuum of HIV-related health care, were:

- How many DEs in the EMA are PLWH/As?
- What are the estimated out-of-pocket costs for those who switch from Medicaid to Medicare Part D prescription-drug coverage?

As it turned out, neither question had a simple, straightforward answer.

For one thing, accurate counts of DEs — whether PLWH/A or not — are difficult to come by, for reasons discussed in detail in section 3.1.1.2. All DE figures mentioned in this report should be considered estimates only, and low estimates at that.

Next, it is unfortunately not possible to describe exactly what Part D benefits will look like for each beneficiary, because PDPs — the private plans through which Part D benefits are delivered — are given great flexibility in deciding precisely which drugs to cover and how to structure cost sharing, such as premiums, deductibles and copays. CMS has propagated a "model benefit," designating certain maximum deductible, premium, copay and coverage-gap amounts, but plans are not required to structure their plans identically. Instead, they are only required to provide a

benefit that is judged by CMS to be of equivalent value to the model benefit. As well, unlike under Medicaid, Part D beneficiaries are not certain to receive every drug prescribed to them by a physician, nor must a plan charge only one level of copays. Plans may require beneficiaries to try equivalent drugs to the ones they have been prescribed; they may charge varying levels of copays, some higher than the amounts that the model benefit might lead one to think are standard; or they may require beneficiaries to follow an exceptions-and-appeals process before obtaining a drug that the plan may have advertised as "covered."

However, examination of the precise details of each of the approximately four dozen stand-alone PDPs available to Maryland beneficiaries was outside the scope of the planning council's research request, as it would not have been feasible in the limited time available. For this reason, the analysis contained in section 3, "Understanding Medicare Part D," which is based on CMS's model benefit, may not reflect a beneficiary's precise experience of any given PDP. Moreover, accurate counts of DEs are hard to come by, as is discussed in greater detail in section 3.1.1.2, and so all DE figures mentioned throughout this report should be considered estimates only.

Finally, determining the precise effects of the switch to Part D is complicated somewhat by the fact that the new program is subsidized for poor people not only by the federal government — an official feature of the program — but also, in Maryland, by SPDAP and MADAP. SPDAP and MADAP have announced plans to subsidize Part D benefits for all Maryland beneficiaries with incomes less than 500 percent FPL. The combination of federal and state subsidies means that more Marylanders will receive a low-cost prescription drug benefit than ever received one before.

The information presented in section 3 of this report concerns only the Part D benefit and the federal government's Part D subsidies, restrictions and costs. MADAP and SPDAP subsidies are discussed in section 4 of this report, "Planning Council Areas of Concern."

3. UNDERSTANDING MEDICARE PART D

Since 1966, the federal government's Medicare program has provided various health-care benefits to people 65 and over, as well as to the disabled. But while Medicare paid for visits to doctors and for hospitalization, it did not offer its beneficiaries any help with their medication costs until the Medicare Modernization and Improvement Act of 2003 was enacted, on December 8 of that year.

Among other things, the MMA created Medicare Part D, an optional, outpatient, prescription-drug benefit that went into effect on January 1, 2006. To tide some beneficiaries over during the two-year wait between enactment and implementation, the MMA also created the Medicare discount drug card, which offered its bearers 10-25 percent discounts on the cost of their prescriptions, with a $600 subsidy for lower-income beneficiaries; the Medicare discount card program is defunct as of January 1, 2006.

Discussed in the media and promoted by the White House primarily in terms of the effects the program would have on senior citizens, who had never before had an age-based medication benefit, Medicare Part D also affects one class of beneficiary — DEs — that already enjoyed prescription drug coverage through Medic*aid*, the combined state and federal program that provides health-care benefits to some kinds of lower-income beneficiaries. DEs lost their Medicaid drug benefits as of January 1, 2006, by which time CMS planned to have automatically enrolled ("autoenrolled") them in a Medicare Part D plan.

According to a Kaiser Family Foundation (KFF) analysis of CMS-released data, as of January 13, 2006, there were 43,404,884 Medicare beneficiaries in the United States, including 23,750,661 Medicare beneficiaries with some form of Medicare prescription drug coverage, either through a Part D plan, or as federal retirees, or through employer plans that receive retiree drug subsidies from the federal government. Of the more than 23 million beneficiaries with prescription drug coverage, 5,600,009 were DEs autoenrolled into Part D, by CMS's accounting. On the local level, also as of January 13, 2006, Maryland was home to 708,981 Medicare beneficiaries, of whom 414,608 had Medicare prescription drug coverage, including 56,536 DEs autoenrolled into Part D (KFF 2006b).

Readers may be familiar with administration claims to have enrolled approximately 24 million people in the Part D drug benefit, such as in President Bush's weekly radio address of February 11, 2006 (WH 2006). However, as can be seen in table 1, which is based on CMS's own data, at most only about 9.1 million people now have drug coverage that they did not already have before the advent of Part D, as opposed to the approximately 15 million federal, military and other retirees whose drug plans were always administered or subsidized by Medicare ("Medicare beneficiaries with non-Part D drug coverage"). And the number of people enjoying a new benefit under Part D may be even lower than CMS's numbers suggest. According to February 2006 analysis by the Medicare Rights Center (MRC), "at most 3.2 million people [nationwide] have new drug coverage as a result of Part D" (MRC 2006c).

Table 1
Medicare Beneficiaries with Prescription Drug Coverage, as of January 13, 2006

	Maryland	*United States*
Medicare beneficiaries	708,981	43,404,884
With drug coverage	414,608	23,750,661
Part D*	136,628	9,151,840
Autoenrolled	56,536	5,600,009
Self-enrolled	80,092	3,551,831
Non-Part D**	277,980	14,598,821
Drug coverage status unknown	294,373	19,654,223

* Because CMS planned to autoenroll all DEs, it is assumed that those who self-enrolled are *not* DEs.

** Non-Part D, Medicare-administered drug coverage is received through Medicare Advantage (formerly Medicare + Choice) plans, those private employer plans receiving retiree drug subsidies, and federal and military retirement plans (such as Tri-Care).

Source: Adapted from a Kaiser Family Foundation table (2006b).

3.1 Eligibility for Part D Benefits

Medicare Part D is available to anyone who is eligible for Medicare, i.e., people 65 and over, or people under 65 with either a Medicare-recognized disability or with kidney disease. For the purposes of this report, it is important to understand that being HIV positive alone is *not* a qualification for Medicare (although there is a limited number of HIV-specific disabilities that do qualify, as well as HIV-related kidney disease), while having AIDS *is* a qualification for Medicare. Therefore, PLWH/As could be eligible for Part D benefits under any of four scenarios:

- HIV positive (not a qualification) with one of the small number of recognized HIV-related disabilities (qualified by disability).
- HIV positive (not a qualification) with a non-HIV-related disability (qualified by disability).
- HIV positive (not a qualification) with AIDS (qualified by AIDS).
- HIV positive (not a qualification) and over 65 (qualified by age alone).

Regardless of the qualifying factors, anyone who becomes eligible for Medicare is eligible for the Medicare Part D prescription-drug benefit, and, depending on income, may also be eligible for federal subsidies toward Part D costs.

3.1.1 Dual Eligibility

For people under the age of 65, some of the eligibility requirements for Medicaid and Medicare are similar. Essentially, having a mental or physical disability that will prevent one from working for a year or more, or that is expected to result in death, is a necessary qualifying factor for non-senior citizens in both programs. In addition, Medicaid applies a means test: a higher-income person with a disability might only be eligible for Medicare, then, while lower-income people with disabilities might be eligible for both. The overlap in eligibility requirements for these programs has resulted in a distinct class of Part D-eligible beneficiaries: those enrolled in both Medicare (because of a disability, or a condition such as AIDS) and Medicaid (because of their low incomes, among other factors). Beneficiaries in this class are known as “dual eligibles.”

About 14 percent of Medicaid enrollees are DEs, compared to about 18 percent of Medicare beneficiaries (KFF 2005a). Of people with HIV/AIDS who are in some form of medical care, about 13 percent are DEs (KFF 2004). Nationwide, DEs tend to be severely disadvantaged in terms of income, health and other key quality-of-life indicators when compared to other Medicare recipients. Almost three quarters of DEs earn less than $10,000 per year, compared with only 12 percent of non-DE Medicare beneficiaries (KFF 2005a). DEs are also in poorer health ("83 percent report fair or poor health versus 57 percent" of non-DE Medicare beneficiaries); less educated (49 percent are high school graduates, versus 75 percent of non-DE Medicare beneficiaries); more likely to be minority (43 percent versus 16 percent); and more likely to be in a nursing home (19 percent versus 3 percent) (Baugh 2005).

Special considerations surround this population and Medicare Part D because:

- Unlike senior citizens, DEs were already receiving a comprehensive, inexpensive prescription-drug benefit through their state's Medicaid programs.
- As of January 1, 2006, DEs lost their eligibility for Medicaid prescription-drug benefits and should have been automatically enrolled in Medicare Part D plans.[2]
- Under Part D, DEs qualify for varying levels of federal and, in Maryland, state subsidies (discussed in section 4.1.1.4) to help them cover the costs that they would otherwise incur under Part D's standard benefit (and which, for some, would have represented significant increases in personal drug costs over the old Medicaid drug benefit).

The planning council's reasons for requesting this report had to do with concerns about the effects on HIV-positive DEs of their forced switch from Medicaid prescription-drug benefits to Medicare Part D prescription-drug benefits. The planning council's concern stems from the fact that the interaction of Medicare and Medicaid programs for DEs is complicated. Medicaid and Medicare both provide a multitude of services and types of care. Medicare provides a greater range of certain kinds of services, albeit with higher cost-sharing requirements than Medicaid and with gaps in its coverage of long-term and other care. Prior to January 1, 2006, of course, there was also no prescription-drug benefit available through Medicare. Therefore, Medicaid plays several important roles for DEs:

- Medicaid pays some or all of DEs' Medicare cost sharing.[3]
- Medicaid assists with gaps in Medicare's unskilled long-term care and vision and dental coverage.
- Prior to January 1, 2006, Medicaid assisted with prescription drug costs (CMA 2005b).

Medicaid assistance with Medicare costs is the only benefit that some higher-income DEs are entitled to, while lower-income DEs are entitled to Medicaid-provided health services as well (including, up until January 1, 2006, prescription drug assistance). Those DEs entitled to full Medicaid services are referred to as "full-benefit dual eligibles" (FBDEs); the rest are "partial-benefit dual eligibles" (PBDEs). States are free to structure their Medicaid systems such that they extend more benefits than under the federally-envisioned version of Medicaid, such as — prior to January 1, 2006 — extending prescription-drug benefits to higher-income DEs who otherwise would only have qualified for assistance with Medicare costs.

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[2] Those who are only eligible for Medicaid, however, will continue to receive benefits through one of Maryland Medicare's seven managed care organizations (MCOs), known collectively as HealthChoice.
[3] "Medicaid contributes nearly 20 percent of all personal national healthcare spending" (CMA 2005b).

Maryland is one of the states that exercises this option, covering its FBDEs through Medicaid and offering prescription drug assistance to higher-income DEs through its Maryland Medicaid-administered Pharmacy Programs (Maryland Pharmacy Assistance Program, or MPAP, and Maryland Pharmacy Discount Program, or MPDP). Nationwide, and prior to January 1, 2006, "[m]ore than 90 percent of those who [were] dually eligible rel[ied] on Medicaid's prescription-drug benefit, with an average use of more than three prescriptions per month" (CMA 2005b).

3.1.1.1 Dual Eligibility in Maryland

In 2003, according to the latest figures available from the Kaiser Family Foundation's State Health Facts web site, there were approximately 94,000 Marylanders who had either full or partial dual eligibility status at some point during the year. Of these, about 70,000 were FBDEs, while about 24,000 were PBDEs.

Table 2

Dual Eligibility in Maryland, 2003

Total dual eligibles in Maryland	94,000
Full-benefit dual eligibles	70,000
Partial-benefit dual eligibles	24,000
Total Medicaid spending* for all DEs	$1,643,000,000
Total spending on drugs prescribed to DEs	$210,000,000
(Drug costs as proportion of total spending)	(12.8%)
Spending on drugs per DE	$2,234
State spending on drugs per FBDE	$1,500
DEs as proportion of Maryland Medicaid enrollees	11%

* State and federal spending combined.

Source: KFF 2005b

The Part D program does not distinguish between PBDEs and FBDEs. Indeed, under Part D, some PBDEs are treated identically to FBDEs. This report considers distinctions between PBDEs and FBDEs, however, because, prior to Part D, these two categories of DEs received different levels of drug benefits in Maryland.

One useful means of distinguishing between PBDEs and FBDEs is by income, although it is important to remember that Medicaid tests enrollees' assets or resources, as well. In Maryland, FBDEs consist of those DEs with annual incomes below 75 percent FPL, while PBDEs have incomes above that level but not exceeding 135 percent FPL.

Maryland Medicaid serves its DEs through what is known as "fee for service," a system in which recipients may choose their doctor and pharmacy. This is as opposed to serving them through what is known as a Medicaid managed care organization (MCO), which functions similarly to a health maintenance organization (HMO). With some exceptions, Maryland DEs may not participate in HealthChoice, Maryland Medicaid's MCO (Flint 2005).

Before the advent of Medicare Part D, all Maryland DEs received their drug benefits through Maryland's Medicaid system, but only FBDEs were served through the program referred to specifically as "Medicaid." PBDEs with incomes less than 116 percent, but above the level that would make them FBDEs, received their prescriptions through MPAP, while those with incomes less than 135 percent FPL received their prescriptions through MPDP, as did other, non-

Medicaid-eligible individuals with incomes up to 175 percent FPL. Both MPAP and MPDP are administered by Maryland Medicaid under a waiver to section 1115 of the federal Medicaid regulation (and so are sometimes referred to as "1115 waiver programs"), which is why individuals with incomes above 135 percent FPL could be included. For the purposes of this report, all individuals with incomes below 135 percent FPL are considered dually eligible.

Table 3
Dual Eligible Prescription-drug Benefits in Maryland: Prior to Medicare Part D

Incomes less than…	*Program delivering drug benefits (before January 1, 2006)*
135 percent FPL	Maryland Pharmacy Discount Program; also served non-DEs, up to 175% FPL
116 percent FPL	Maryland Pharmacy Assistance Program
75 percent FPL	Maryland Medical Assistance

Source: MMAP 2004

Another program that is often mentioned in the context of Maryland's public health assistance programs is the Maryland AIDS Drug Assistance Program, or MADAP. MADAP helps low- to moderate-income Marylanders afford HIV medications; however, Medicaid recipients were never eligible for MADAP assistance. Now that Medicaid recipients receive their drug benefits through Medicare, MADAP plays an important role in helping to subsidize the Part D benefit for Maryland beneficiaries, as discussed in section 4.1.1.4.

3.1.1.2 Dual Eligibles with HIV/AIDS

One of the planning council's research questions concerned how many of the EMA's PLWH/As are DEs. As it turns out, this is a difficult question to answer, because (1) simply determining the precise number of DEs as a whole is problematic, and (2) HIV status is not necessarily part of a Medicare or fee-for-service Medicaid client's record.[4] However, by using proxy indications of HIV status, it is possible to arrive at a baseline minimum figure for the number of HIV-positive DEs residing in the Baltimore EMA.

The difficulty of determining the exact number of DEs, in a state or nationwide, is due to characteristics of the data organization methods used by both Medicare and Medicaid. A 2005 study by a CMS analyst found that "[n]either the Medicare nor the Medicaid systems, by themselves, permit complete and accurate reporting of dual enrollees." Of the two programs, according to the study, only Medicaid makes specific mention of dual eligibility in clients' records. However, even this "dual eligibility flag" has only been required since 1999 and, nationally, "reporting remains inconsistent" (Baugh 2005). Therefore, it is possible that queries of a state's Medicaid data for dual eligibles will return fewer than the actual number of dual eligibles.

Another obstacle to determining the precise number of HIV-positive DEs in the Baltimore EMA is the fact that HIV status is not necessarily part of clients' records in the Medicare or Medicaid

[4] HIV status is part of the records of Medicaid clients served through MCOs (for which Maryland DEs are not eligible), in the following sense: Medicaid makes payments on behalf MCO clients at various rates, depending on certain of that patient's specific health-care needs. HIV and AIDS are two conditions for which specific rates are paid; a query for patients paid for at these rates could be used to generate a count of PLWH/As in Maryland MCOs, but this count would not include DEs (Flint 2004).

databases. A review of each client's medical file could determine HIV status, but this approach would be time-consuming and risk compromising patient confidentiality. But there is another possible approach. Though Medicare and Medicaid databases do not necessarily include clients' HIV status, the databases would contain information about payment for certain services (e.g., viral load tests) or medications (e.g., antiretroviral drugs) that only PLWH/As would be expected to receive, as well as diagnosis codes for HIV-related conditions. These proxy measures allow the establishment of a baseline number of HIV-positive DEs in the Baltimore EMA.

At the planning council's request, the Maryland Department of Health and Mental Hygiene (DHMH), which administers Maryland Medicaid, queried the Maryland Medicaid Information System (MMIS). Table 4 shows Maryland Medicaid's official number of fee-for-service Medicaid clients (including MPAP and MPDP clients) in Maryland and in each of the Baltimore EMA jurisdictions whose Medicaid record for the period of July 2004 through June 2005 showed all of the following:

- At least two prescription-drug claims for an HIV-specific drug.
- At least two diagnosis codes for HIV-related conditions on inpatient, outpatient or physician claims.
- A dual eligible code, which indicates enrollment in Medicare (Flint 2006).

Table 4
DEs in Maryland and the Baltimore EMA, by Jurisdiction, May-October 2005

	Anne Arundel County	*Balt. City*	*Balt. County*	*Carroll County*	*Harford County*	*Howard County*	*Queen Anne's County*	*EMA Total*
Number	40	739	98	3	20	11	2	913
% of EMA	*4.4%*	*80.9%*	*10.7%*	*0.3%*	*2.2%*	*1.2%*	*0.2%*	*100%*
% of State	*3.4%*	*62.9%*	*8.3%*	*0.3%*	*1.7%*	*0.9%*	*0.2%*	*77.8%*

Source: Flint 2006.

Maryland-wide, there were 1,174 DEs (partial and full benefit, including MPDP and MPAP clients) who met the qualifications listed above. Of these, 913 resided in the Baltimore EMA. Baltimore City had the greatest number of DEs — 739, or 80.9 percent of the EMA total — during the period in question, followed in descending order by Baltimore County (98; 10.7 percent of the EMA total), Anne Arundel County (40; 4.4 percent of the EMA total), Harford County (20; 2.2 percent of the EMA total), Howard County (11; 1.2 percent of the EMA total), Carroll County (3; 0.3 percent of the EMA total) and Queen Anne's County (2; 0.2 percent of the EMA total) (Flint 2006).

As noted earlier, there is good reason to suspect that these numbers may be low. For example, a 2000 study by the Maryland AIDS Administration examined dually eligible AIDS cases in Maryland, 1996-1998, using a different method than the one described above. In 1996, the study found, there were 552 dually eligible AIDS cases in Maryland; in 1997, there were 842, or an increase of 52.5 percent over the prior year; and, in 1998, there were 1,002, or an increase of 19.0 percent over the prior year (Flynn, Landrigan and Solomon 2000). It seems likely that the number of dually eligible AIDS cases would have continued to rise in the ensuing years, and — while it is

impossible to estimate a reliable rate of increase with data from only three consecutive years — an increase of only 172 cases since 1998, or 17.2 percent over more than six years, seems small.

On the other hand, KFF estimates that 12-13 percent of people with AIDS who are in care are DEs (KFF 2004). At the end of 2004, there were 7,640 living AIDS cases in the Baltimore EMA (MAA 2005), which would lead one to expect the EMA's dually eligible PLWH/As to number at least 917, a similar number to the 913 reported above.

Absent a more active and detailed examination of the Medicaid and Medicare databases, for which high-level permission and expert assistance would be required — not practical for the current project, in other words — the figures presented in table 4 represent the best possible answer to the planning council's question at this time.

3.1.1.3 Autoenrollment of Dual Eligibles

While all other Part D-eligible individuals were required to enroll on their own in a Part D plan, CMS directed that any DE who had not enrolled in a plan by December 31, 2005 would be automatically enrolled ("autoenrolled") in one. On its face, such a plan had some merit, in the sense that DEs' medication benefits under Medicaid would cease as of January 1, and — since a public information campaign urging voluntary enrollment might not reach or convince all DEs in time — autoenrollment in any Part D plan would be preferable to losing medication coverage entirely.

CMS's plan was that, by August of 2005, CMS would assemble a list of existing dual eligibles nationwide. In addition to notifying these DEs of the upcoming change, and of their option to choose their own plan, CMS set up an automated process by which these DEs would be enrolled in a PDP on January 1 if they had not yet chosen a plan. CMS announced that autoenrollment would proceed "according to a set of guidelines that minimizes disruption of [beneficiaries'] current care delivery" (CMS 2005a). However, CMS did not plan to use any DE's actual prescription records to evaluate whether or not a given plan would be a good fit for that DE or not. In terms of actual medication needs, in the words of one advocacy organization, CMS would essentially "randomly assign" DEs to a plan (MRC 2005b). As a safeguard, then, CMS permits anyone that could have been autoenrolled to change plans once a month. All other enrollees may only change plans during the annual enrollment period, November 15-December 31 of each year (MRC 2005b).

DEs were allowed to begin enrolling in their own plans — i.e., opting out of the autoenrollment process — starting November 15, 2005, although, as is discussed in section 4.2.2.3 of this report, technical glitches plagued those DEs who chose to do so (Forbes 2006).

As mentioned in section 3.1.1.1, by January 13, 2006, CMS had automatically enrolled 56,536 of Maryland's DEs. Obviously, this number is quite a bit smaller than the 94,000 total DEs in Maryland in 2003 referred to in section 3.1.1.1 (KFF 2006b). It is not clear if this discrepancy is because of a large number of DEs opting out of autoenrollment, or if it represents CMS's failure to completely execute its autoenrollment plan. Media reports suggest the latter, as discussed in section 4.2.2.3.

3.2 Structure of Part D Benefits

Medicare Part D is an optional, outpatient, prescription-drug plan that is intentionally designed to offer many different options in the structure and cost of coverage. Though administered and funded by CMS, Medicare Part D benefits are actually delivered by private or non-profit health-care companies and organizations, such as Aetna, Kaiser Permanente and so forth.

Within a complex web of federal guidelines, each of these entities offers one or more Medicare Part D PDPs, through which enrollees receive varying levels of benefits (according to income and other factors) for those prescription drugs covered by their plan and obtained at pharmacies in that plan's network. Since the nature of the coverage provided by PDPs can vary, many companies offer several PDPs, each tailored to cover only certain drugs (as allowed by CMS), though there are certain drugs, such as HIV antiretrovirals (ARVs) that all plans are required to cover. As of November 13, 2005, there were 47 PDPs available to Maryland Medicare beneficiaries (CMS 2005f).

Though CMS has specific requirements that all Part D drug plans must meet, PDP providers have wide latitude in determining which drugs to cover and when to stop covering them, how much to charge enrollees and whether or not to "tier" or create "preferred' and "non-preferred" lists of the drugs they cover (Gottlich 2005). According to the Medicare Rights Center, a Medicare consumer advocacy organization, "you may never see a plan exactly like the basic plan outlined in the law [that created Medicare Part D]. Plans can structure their benefit differently as long as the overall value is at least as good as the Medicare basic plan" (MRC 2005b).

3.2.1 Prescription Drug Plan Requirements

According to analysis performed by the Medicare Rights Center, all Medicare Part D prescription drug plans (PDPs) must follow certain requirements:

- PDP drug coverage value must be "the same or greater than the basic plan outlined in the law" that created Part D.
- Deductibles "cannot be more than $250 in 2006" (standard benefit).
- "Catastrophic coverage must be at least as good as it is under the plan outlined in the law" that created Part D. (Catastrophic coverage is defined in section 3.2.3.1.)
- "Plans must cover at least two drugs in each drug class in their formulary…[in addition to] all or substantially all drugs in six categories: antidepressants, antipsychotics, anticonvulsants, antiretrovirals (AIDS treatment), immunosuppressants and anticancer." (Part D's drug coverage requirements are detailed in section 3.2.2).
- Plans must establish and publicize an exceptions and appeals process in the event that "a non-covered drug is medically necessary." (Exceptions and appeals processes are explained in section 3.2.2.1.)
- PDP pharmacy networks must "meet…federal standards for convenient access."
- Pharmacy network and formula details must be "easily available," though "some information is only required [to be released] upon request."
- "Plans must have a Medicare-approved transition process for members who change care settings (such as going from a hospital to a nursing home) and for new members whose condition has been stabilized on medications that are not on the plan's formulary or if the plan places certain restrictions on coverage of particular drugs, such as prior authorization, step-therapy, and dosage limits…."
- "Plans must give nursing home residents a one-time supply of non-formulary medications while an exception is being processed" (MRC 2005b).

3.2.2 Part D Covered Drugs

All Part D PDPs must cover "all medically necessary drugs," but plan providers enjoy wide latitude in interpreting this requirement. As a result, one PDP might offer substantially different coverage — in terms of the costs of and processes for obtaining certain drugs — from another PDP. This raises the possibility that, for each beneficiary, some plans may be more suitable than others. The burden is on beneficiaries to evaluate the coverage offered by a given PDP before enrolling, and to do so carefully: except for those who were autoenrolled into a PDP (i.e., dual eligibles), no beneficiary may change plans more often than once a year, and then only during the "annual coordinated election period" (ACEP), November 15-December 31 of each year (MRC 2005b). But no matter how carefully beneficiaries evaluate a PDP, that PDP may discontinue coverage of a drug throughout most of the year. Also, certain drugs are excluded from coverage under Part D.

Under CMS rules, PDPs must provide coverage for all medically necessary drugs, biological products and insulin, and their drug formularies must be designed to provide "access to a broad range of medically appropriate drugs to treat all disease states and to ensure that the formulary design does not discriminate or substantially discourage enrollment by certain groups," based in large part on CMS's and the individual PDP's interpretation of "medically necessary," as opposed to that of the prescribing physician (CMS 2005b). Compliance with this requirement is managed through a system of "therapeutic categories" of medications, most of which are divided into associated pharmacologic classes (also known as drug classes). For example, the therapeutic category "antidepressants" is divided into three pharmacologic classes: monoamine oxidase inhibitors, reuptake inhibitors, and "other antidepressants" (USP 2004a).

Table 5
Part D Therapeutic Categories and Pharmacologic Classes: Total Numbers

Therapeutic categories	41
With no pharmacologic classes	9
With pharmacologic classes	32
Pharmacologic classes	137
Unique therapeutic categories and pharmacologic classes	146

Source: USP 2004a

There are 41 therapeutic categories, 32 of which contain pharmacologic classes and 9 of which have no pharmacologic classes. The official list of therapeutic categories and pharmacologic classes, known as the model guidelines, was created by the United States Pharmacopeial Convention, Inc. (USP), as required under the MMA (USP 2004a).

The categories and classes described above are used to define which drugs a PDP must cover. CMS requires that all PDPs cover and ensure uninterrupted access[5] to a majority of drugs in each

[5] CMS's definition of "uninterrupted access" includes access obtained through "exceptions processes," i.e., the processes by which a beneficiary can appeal a PDP's decision not to make a specific drug available to that beneficiary. This definition has the advantage of providing a mechanism through which a beneficiary can get access to a non-covered drug, and the disadvantage of allowing a PDP to state that it offers

pharmacologic class in the following six therapeutic categories: antidepressants, antipsychotics, anticonvulsants, antiretrovirals,[6] immunosuppressants and antineoplastics. In addition, all PDPs must also cover at least two drugs (and/or any CMS-specified drugs) from each of the remaining unique therapeutic categories and pharmacologic classes, as well as adopting an exceptions and appeals process through which beneficiaries can attempt to obtain non-covered drugs prescribed by their physicians. PDPs that meet these requirements satisfy CMS's requirement that they provide access to "all medically necessary" drugs (CMS 2005b). As can be seen, however, plans can meet these requirements without pledging themselves to providing every specific drug a beneficiary could be prescribed, creating the potential for differences of opinion between the prescribing physician and the PDP concerning the definition of "medically necessary."

Also, the requirement that beneficiaries be able to access all medically necessary prescriptions does not mean that each of the drugs a PDP covers must be equally readily available through that PDP's normal prescription process.[7] As long as the plan is not found by CMS to discriminate among beneficiaries (such as by discouraging participation by higher-cost beneficiaries or beneficiaries with specific conditions), PDP sponsors are permitted to manage their costs through the use of various "utilization management tools":

- "Step therapy" (i.e., the requirement that beneficiaries follow a PDP-designated sequence of prescriptions before obtaining a particular drug).
- Differing levels of copayments for different drugs.
- A tiered pricing system (e.g., the designation of "preferred" and "non-preferred" drugs).
- Required prior authorization from the prescribing physician for certain drugs (CMS 2005b).

Finally, PDPs may discontinue coverage of, or change the cost sharing for, any drug at any point throughout most of the year.

3.2.2.1 Exceptions and Appeals

As noted earlier, Part D PDPs are not required to offer access to every drug that an enrollee might be prescribed, even if the drug is on the list of drugs that may be covered under Part D. An exceptions-and-appeals process exists to allow Part D PDP enrollees to challenge a PDPs decision not to cover a specific prescribed drug, or to request a change to the costs associated with that drug under the PDP's cost-sharing structure. An exception is an enrollee's first request that a non-preferred drug be made available to him or her. An appeal is an enrollee's request that their PDP reconsider a negative response to an exception. CMS requires that PDPs structure the exceptions and appeals processes such that "a non-preferred drug could be covered under the terms applicable for a preferred drug" (FR 2005:4352).

"uninterrupted access" to these drugs when in fact that access is available only through the appeals process, an obscure distinction that may confuse some beneficiaries. (CMS 2005b)

[6] As of June 2005, the following HIV/AIDS drugs must be offered by every PDP: Stavudine; Tenofovir; Zalcitabine; Zidovudine; Amprenavir; Atazanavir; Fosamprenavir; Indinavir; Lopinavir and Ritonavir; Nelfinavir; Ritonavir; Saquinavir; Enfuvirtide; Delavirdine; Efavirenz; Nevirapine; Abacavir; Abacavir, Lamivudine and Zidovudine; Abacavir/Lamivudine; Didanosine; Emtricitabine; Emtricitabine and Tenofovir; Lamivudine; Lamivudine; and Zidovudine (CMS 2005g).

[7] Some beneficiaries might not consider a drug (1) for which prior authorization is required, (2) that can only be obtained through their PDP's exceptions and appeals process, or (3) that incurs a much higher copay than other drugs offered by that PDP, to be "covered" in the common sense of the word. However, one media account suggests that some PDP marketing materials may indeed be advertising such drugs as "covered" (Andrews 2006).

There are several scenarios under which a PDP enrollee may request an exception to a plan's formulary (i.e., that the plan cover a drug or change the nature of its coverage of a drug):

- Arriving in a new plan with a prescription for a drug that that plan does not cover.
- Being prescribed a new drug that the plan does not cover.
- Receiving notice that a plan will no longer cover one of that enrollee's prescribed drugs, a decision plans are permitted to make throughout most of each year (MRC 2005b).

CMS is purposefully vague about how PDPs must structure their exceptions and appeals processes, "to avoid a situation where a plan's cost-sharing rules are effectively driven by the…exceptions criteria," with the result that PDP providers exercise considerable discretion in designing their exceptions and appeals processes. Before an exception request may proceed, for example, the enrollee's physician must first submit a statement finding that "the preferred drug [i.e., the drug that the plan claims is equivalent to the prescribed, "non-preferred" drug] either would not be as effective…or would have adverse effects for the individual," but it is up to the PDP to decide whether physicians must report such findings orally or in writing, what additional information must accompany the statement (e.g., a detailed patient history or physical evidence), what format written statements must take, and — finally — whether such a statement alone would be sufficient grounds for granting the exception, or whether the patient would still be required to try other medications in the plan's formulary prior to receiving the prescribed medication. Further, PDPs are free to design their own procedures for evaluating whether a drug "would not be as effective…or would have adverse results," subject to CMS review (FR 2005: 4352).

Table 6
Part D Exceptions and Appeals Response Timeframes: Standard and Expedited

	Standard Timeframe	*Expedited Timeframe*
Exceptions	72 hours	24 hours
Appeals	7 days	72 hours

Source: FR 2005, p. 4,345

In the event that an enrollee is prevented from accessing a prescribed drug, time may be of the essence, so CMS requires that PDPs establish "expedited procedures when the standard [exceptions and appeals] timeframes could seriously jeopardize an enrollee's life, health or ability to regain maximum function." A doctor's statement of the urgency of the enrollee's need is required in order for an exception or appeal to be expedited. The standard timeframe within which PDPs must return responses to exception requests is 72 hours, with expedited responses due within 24 hours. Responses to appeals must be answered within 7 days, as the standard timeframe, while the expedited timeframe is 72 hours (FR 2005:4345).

However, there are two circumstances in which, according to an analysis by KFF, CMS regulations forbid enrollees to request that drugs with higher copays be covered at a lower copay rate:

- "If the plan has a separate tier for generic drugs, an enrollee cannot get an exception to cover the non-preferred drug at the generic drug cost…."

- "[I]f the plan has a separate tier for high-cost or unique drugs, such as genomic and biotech products, those drugs are not eligible for tiering exceptions" (KFF 2005c).

According to KFF's analysis, these prohibitions are of CMS's devising and are not required by the MMA (KFF 2005c).

3.2.2.2 Part D Excluded Drugs

There are certain drugs that Part D PDPs are not permitted to cover. These include any drugs that are covered under Medicare Parts A or B, and any drug in eight categories that federal law permits state Medicaid programs to exclude: weight loss or gain, fertility, cosmetic or hair growth, cough or cold relief, vitamins and minerals, non-prescription (over-the-counter) drugs, barbiturates, and benzodiazepines (KFF 2003).

Maryland Medical Assistance (Medicaid) will cover some of these drugs for Maryland dual eligibles, however, as was the case prior to January 1, 2006 as well. The covered categories are: weight loss or gain, benzodiazepines, barbiturates, prescription vitamins and minerals, certain cough and cold medicines and some over-the-counter drugs (CMA 2006). Maryland Medicaid will receive federal matching funds for expenses in these categories (Coats 2006).

3.2.3 Part D Costs

Medicare Part D PDPs operate in a manner familiar to any customer of private health insurance: depending on one's income level and on the structure of the particular PDP, there are varying levels of premiums, deductibles and copay or coinsurance costs.

Without direct examination of a given beneficiary's PDP, however, it is not possible to predict precisely what that beneficiary's costs will consist of. This is because PDPs do not have to offer standard, uniform coverage and can instead structure their plans in any manner that offers the same overall value as the basic plans described in the MMA. In particular, premiums will vary by area. CMS predicts that the national average premium cost will be $32.20 per month for 2006 (MRC 2005b).

Part D beneficiaries can be divided into two broad groups, those receiving the standard benefit and those receiving extra help.

3.2.3.1 The Standard Benefit

Part D beneficiaries with incomes above 150 percent FPL receive the standard benefit. In 2006, as far as CMS is concerned (i.e., before any help from state or local agencies), these beneficiaries are responsible for:

- $32.20 monthly premium (the estimated average monthly premium, nationwide, for 2006).
- $250 annual deductible.
- $500 in annual copays (25 percent of the next $2,000 in medication costs after the deductible is paid).
- The coverage gap, commonly referred to as the "donut hole": after medication costs exceed $2,250, Medicare shifts the responsibility for 100 percent of medication costs to the beneficiary until those costs exceed $5,100.
- Catastrophic coverage: once medication costs exceed $5,100, copays equal to 5 percent of medication costs.

In other words, beneficiaries receiving the standard benefit must pay — or have paid on their behalf — $3,600 before reaching "catastrophic coverage."[8] This cost is in addition to their monthly premium, which will total approximately $387 in 2006 ($32.20 x 12).

Table 7
Part D Standard Benefit: Costs to Client Absent State Help

Monthly premium	$32.20
Annual deductible	$250
Annual copays	$500
Coverage gap (donut hole)?	Yes (client pays $2,850)
Catastrophic coverage (above $5,100 in drug costs)	$2/$5 copays
Annual costs to client (absent state help)	$3,600 + premium + $2/$5 copays

Source: MRC 2005b

PDPs are free to offer more valuable benefits to their enrollees, such as assistance with donut hole costs. However, of the six PDPs in Maryland offering assistance with donut hole costs (as of November 13, 2005), only one (PacifiCare Comprehensive Plan) has a monthly premium under $40 ($38.16). Notably, the PacifiCare Comprehensive Plan covers only 78 of the 100 drugs most commonly used by Medicare beneficiaries, the lowest number of these drugs covered by any Maryland plan (CMS 2005f).

3.2.3.2 Extra Help

A Part D beneficiary receiving the standard benefit could conceivably incur considerable expense in the course of a year, but financial assistance is available to lower-income Part D beneficiaries. An "extra help" subsidy — varying according to income — may be paid through the Social Security Administration's (SSA) Supplemental Security Income (SSI) program on behalf of clients with incomes below 150 percent FPL (such as DEs) and whose liquid resources do not exceed SSI limits.

DEs who are autoenrolled in a PDP should also automatically receive extra help at the level appropriate for their annual income and resources. Other individuals who are not DEs may also be eligible for extra help, but the responsibility to apply for the subsidy is theirs. Part D-eligible individuals who think they may be eligible for extra help may apply either through their state's Medicaid agency or through an SSA office, similar to applying for SSI (TAEP 2005).

Clients eligible to receive SSI's extra help can be divided by income into two main groups: those who receive the low-income partial subsidy, or LIPS (incomes less than 150 percent FPL), and those who receive the low-income full subsidy, or LIFS (incomes less than 135 percent FPL, with a further subgrouping for those with incomes less than 100 percent FPL). Along with varying levels of assistance with premium, deductible and copay costs, neither LIPS nor LIFS recipients experience the donut hole, as a result of the extra help subsidy paid on their behalf by SSI.

[8] This cost is the total of the $250 deductible + the $500 copay (25 percent of next $2,000) + $2,850 (100 percent of donut hole costs).

Table 8 **Part D Low Income Partial Subsidy (LIPS): Costs to Client Absent State Help***	
Monthly premium	$0-32.20
Annual deductible	$50
Annual copays	$765
Coverage gap (donut hole)?	No
Catastrophic coverage (above $5,100 in drug costs)	$2/$5 copays
Annual costs to client (absent state help)	$815 + premiums + $2/$5 copays

* Note: Maryland state help available to these beneficiaries is discussed in section 4.1.1.4.

Source: MRC 2005b

LIPS is available to beneficiaries with incomes below 150 percent FPL whose liquid assets do not exceed the SSI limit. As table 8 shows, in 2006, as far as CMS is concerned (i.e., before any help from state or local agencies), these beneficiaries are responsible for:

- $0-$32.20 monthly premium (the estimated average monthly premium, nationwide, for 2006), on a sliding scale according to income.
- $50 annual deductible.
- $765 in annual copays (15 percent of the first $5,100 in medication costs after the deductible is paid).
- Catastrophic coverage: once annual medication costs exceed $5,100, a copay of $2 (generic medications) or $5 (name-brand medications).

In other words, beneficiaries receiving LIPS must pay — or have paid on their behalf — $815 before reaching "catastrophic coverage,"[9] when their copays will be reduced to $2 (generic medications) or $5 (name-brand medications). This is in addition to the monthly premium, which will total approximately $0-$387 in 2006 (0$-$32.20 x 12), on a sliding scale according to income.

There are two levels of LIFS, one for those with incomes below 135 percent FPL, and one for those with incomes below 100 percent FPL (see table 9). Beneficiaries at neither level pay any premium or deductible, and they do not pay any copays after total medication costs exceed $5,100. In fact, the only difference between the two levels of LIFS beneficiaries is the amount of the required copays:

- Those with incomes less than 135 percent FPL pay $2 for generic medications and $5 for name-brand medications until annual medication costs exceed $5,100, at which point beneficiaries in this category no longer incur costs for medications covered by Part D.
- Those with incomes less than 100 percent FPL pay $1 for generic medications or $3 for name-brand medications until annual medication costs exceed $5,100, at which point beneficiaries in this category no longer incur costs for medications covered by Part D.

[9] This cost is the total of the $50 deductible + the $765 copay (15 percent of first $5,100).

Table 9

Part D Low Income Full Subsidy (LIFS): Costs to Client*

	Incomes <100% FPL	*Incomes <135 % FPL*
Monthly premium	$0	$0
Annual deductible	$0	$0
Annual copays	$1/$3 until drug costs > $5,100	$2/$5 until drug costs > $5,100
Coverage gap (donut hole)?	No	No
Catastrophic coverage (above $5,100 in drug costs)	$0 copays	$0 copays
Annual costs to client (absent state help)	$1/$3 until drug costs > $5,100	$2/$5 until drug costs > $5,100

* There is no Maryland state assistance available to these clients.

Source: MRC 2005b

The amount that beneficiaries in this category must pay — or have paid on their behalf — before reaching catastrophic coverage will vary according to the costs of their medications and the frequency with which they refill prescriptions. For example, a Part D LIFS beneficiary whose monthly medication costs do not exceed $425 would not reach catastrophic coverage during the year ($425 x 12 = $5,100), meaning that he or she would remain responsible for copays for the entire year. Since copays are paid per medication, the total amount of copay costs would depend on the number of prescriptions represented by that $425 monthly cost: 3 medications would require 3 copays ($3-$15 per month); 10 medications would require 10 copays ($10-$50 per month); and so on.

The more expensive a Part D LIFS beneficiary's medications are, the less burdensome these copays would be; ARV medications prescribed to people living with HIV/AIDS (PLWH/As) tend to be expensive. For example, in 2005, the average client receiving HIV-medication assistance through MADAP obtained four HIV drugs per month, the total cost of which — on average — exceeded $5,100 every three months. PLWH/As receiving Part D benefits are likely to be on similar — and similarly expensive — regimens, meaning that they would attain catastrophic coverage status by the end of their third month of coverage, on average. At four drugs per month for three months, then, total annual copays for PLWH/As who are Part D LIFS beneficiaries would equal $12-$36 (for beneficiaries with incomes below 100 percent FPL) or $24-$60 (for beneficiaries with incomes below 135 percent FPL) (Anders 2005). These beneficiaries might receive non-HIV-related prescriptions as well, of course, in which case they could attain catastrophic coverage status even sooner than described here.

3.3 Conclusion

Medicare Part D has widely varying effects on the diverse pool of people who became eligible for this benefit as of its rollout on January 1, 2006. The senior citizens who represent the vast majority of potential beneficiaries never had the option of a public prescription-drug benefit before, but low-income individuals eligible for both Medicare and Medicaid (DEs) previously enjoyed robust and comprehensive drug coverage under Medicaid.

Complicating analysis of Part D's effects is the flexibility built into CMS's regulations, allowing Part D PDP sponsors wide latitude in designing their plan's drug coverage, cost structure and

administrative details. This flexibility is touted by CMS as ensuring the delivery of high-quality services by increasing competition, allowing for creative cost-saving measures and offering beneficiaries multiple drug plans to choose from. But CMS's vague requirements also make it extremely difficult to construct an accurate picture of what the drug benefit will look like in practice for individual consumers.

For example, CMS does not require delivery of a uniform, standard benefit, but instead offers an example of a model plan (the "standard benefit" described in section 3.2.3.1) with certain maximum premiums, deductibles, copays and coverage gaps, as well as "extra help" benefits for lower-income beneficiaries (described in section 3.2.3.2). Actual plans must resemble this model essentially only in terms of total annual costs for an average beneficiary. As a result, a given beneficiary could experience a plan that is markedly different from CMS's model plan, as long as that plan is judged by CMS to offer a benefit that is equivalent in value to the model plan, as determined by analysis of the plan's drug coverage, cost-sharing structure and so on.

Some of the most important differences between PDPs arise from the flexibility that plan sponsors have concerning which drugs they cover, and at what costs to the client, so that, as one analysis found, annual out-of-pocket costs for a given, hypothetical Part D beneficiary — not eligible for "extra help" — could vary by more than 100 percent from one plan to another (CHF 2006). In order for beneficiaries to minimize their costs, they need accurate information about the exact nature of each plan's coverage, but anecdotal media reports suggest that coverage information released by some companies may not have been accurate or up to date (Wolfe 2005), or may employ certain terms (such as "covered drugs") to mean something other than common usage might lead beneficiaries to expect (Andrews 2006).

For DEs, the main difference between Medicare Part D and the Medicaid prescription-drug coverage that was previously available to them is that Part D PDPs might not cover every drug their physicians could prescribe, even if the drug is one of those that Part D plans are allowed to cover. Medicaid, on the other hand, was required to cover every drug made by any manufacturer that participated in a particular state's program, with "the result…that states' Medicaid programs cover[ed] virtually all drugs" (MMAP 2004).

That said, the existence of a basic model plan does allow for baseline analysis concerning the general effects of Part D. *Assuming that a beneficiary is able to easily obtain the medications he or she needs* (an assumption that may not hold true with all PDPs), it is possible to make a broad assessment of the financial impact of coverage available under Part D on lower-income beneficiaries (such as DEs).

For the poorest beneficiaries (incomes under 135 percent FPL):

- Out-of-pocket expenses arise entirely from copays ($1-$2 for generic medications; $3-$5 for name-brand medications).
- Costs are not significantly higher than they were under Medicaid and are lower than they were under the Maryland Pharmacy Assistance Program. (Maryland's pre-Part D prescription-drug programs are described in section 4.1.1.1.)
- Total annual costs depend on total number of prescriptions filled and how quickly the total cost of those prescriptions exceeds $5,100 (likely to be within three months for PLWH/As).

For those with the next-highest range of incomes (below 150 percent FPL):

- Out-of-pocket expenses arise not only from copays but also from premiums and deductibles (both on a sliding scale by income).

- Costs are significantly lower than they were under the Maryland Pharmacy Discount Program. (Maryland's pre-Part D prescription-drug programs are described in section 4.1.1.1.)
- After total annual costs of approximately $1,200 (deductibles, pre-catastrophic coverage copays and premium), copays become $2 (generic medications) or $5 (name-brand medications). Total annual costs depend on total number of prescriptions filled.

All other Part D beneficiaries receive the standard benefit, paying full premiums (around $400 per year), deductible ($250), copays equal to 25 percent of the first $2,000 ($250), 100 percent of the next $2,850 (after which catastrophic coverage is reached), followed by copays equal to 5 percent of the medication's price. In other words, beneficiaries at this level have open-ended and potentially quite large costs; however it is important to remember that beneficiaries at this income level never received a more valuable drug benefit before, and so even their potentially high costs under Part D generally represent an improvement on their costs before Part D.

The information that has been presented in this section concerns only the Part D benefit and its associated subsidies, restrictions and costs. In Maryland, two programs known as SPDAP and MADAP have announced plans to further subsidize Part D benefits for all beneficiaries with incomes less than 500 percent FPL, meaning that a much larger pool of Marylanders will receive a low- or even, in some cases, no-cost prescription-drug benefit than ever received one before. This state-level subsidy of Part D is discussed in greater detail in the next section of this report, "Planning Council Areas of Concern."

4. PLANNING COUNCIL AREAS OF CONCERN

In early 2005, as various policies and regulations concerning the upcoming Medicare Part D benefit were being finalized and published, members of the planning council's Needs Assessment Committee grew aware of a chorus of alarm raised by various public health policy advocacy and watchdog organizations concerning potential negative consequences of the Part D benefit, particularly for the poorest beneficiaries. At the time, Part D was something of a moving target: CMS's final rules were only published in late January of 2005 (FR 2005), and a flurry of updates and changes would follow until and beyond the starting date of the program, January 1, 2006. Planning for the possibility that the Part D switch might affect the continuum of HIV care in the Baltimore EMA and require planning council action, the council requested the use of carryover funds to commission this report, with work to commence on September 1.

4.1 The Planning Council's Questions

The planning council's specific concern was that DEs, who already enjoyed robust prescription-drug benefits under Maryland Medicaid, might see significant increases in their personal medication costs as a result of their mandatory switch to a Part D PDP. In the event that (1) there was a large number of DEs with HIV/AIDS in the Baltimore EMA and (2) the switch to Part D would indeed significantly increase their drug costs, one side effect of Part D might be an increase in the number of PLWH/As in the Baltimore EMA who depended on RWCA Title I funds for services. The increased demand for services might, in turn, require shifts in funding priorities or activation of unused funding categories.

As explained to HRSA in the carryover funds request, the planning council proposed that the support office's research staff investigate whether or not "[p]roposed changes to the Medicare Part D program will…jeopardize [dual eligibles'] ability to obtain needed medication and services…[by] having to pay out-of-pocket deductibles to access a medication program" (PC 2005). Included in this investigation and impact assessment would be explanations of "what specific changes occurred, [analysis of] their impact to RWCA Title I-eligible clients, and…recommendations to address the changes and assist those impacted by the changes." The project's final product would be a report to the council, including recommendations that would help them plan future funding allocations (PC 2005).

The planning council requested answers to two main questions:

1. "Ascertain how many people living with HIV/AIDS are dually eligible in the metropolitan area...."
2. "Verify/estimate out-of-pocket costs for those who go from Medicaid to Medicare Part D prescription coverage…" (PC 2005).

Question 1 is answered in section 3.1.1.2. Question 2 is answered in the following section. The overall impact and planning implications of these findings are discussed in section 5.

4.1.1 Out-of-Pocket Drug Costs: Medicaid versus Medicare Part D

This report uses the term "dual eligibles" to refer to all Medicare beneficiaries who received Medicaid or Medicaid-administered drug benefits prior to January 1, 2006 (i.e., full-benefit dual eligibles, with incomes less than 75 percent FPL, and partial-benefit dual eligibles, with incomes

less than 135 percent FPL). Out-of-pocket drug costs under Part D vary according to income, as discussed earlier in this report.

The following analysis of full- and partial-benefit DEs' old benefits versus their new benefits compares costs incurred at various income levels under the programs through which Maryland DEs previously received their drug benefits (MPAP and MPDP) with costs incurred under the new program, Medicare Part D. As stated above, this analysis is based on CMS's model benefit; actual PDPs could vary considerably from the model benefit as long as they are judged by CMS to offer an equivalent value.

4.1.1.1 Pre-Part D Prescription-drug Programs in Maryland

Table 10 compares the prescription-drug programs that were available to Maryland residents before the introduction of Part D.

Medicaid is the public health insurance program for those with low incomes and in certain categories of medical need. Since 1990, Medicaid has offered a prescription-drug benefit which was required to cover all drugs made by any participating manufacturer, with "the result…that states' Medicaid programs cover[ed] virtually all drugs." Dual eligibles obtained their drugs through Medicaid fee for service, meaning that beneficiaries could fill prescriptions at virtually any pharmacy. While virtually all drugs were covered, those that were not on the program's "preferred drug list" (PDL) required prior authorization. Preferred drugs carried a $1 copay; non-preferred drugs, a $2.50 copay (MMAP 2004). According to Maryland Medicaid, about 55,000 FBDEs received this benefit prior to January 1, 2006 (MAC 2006); as of that date, no one who is eligible for Medicare is eligible to receive the Medicaid prescription-drug benefit.

Low-income DEs who did not qualify for full Medicaid benefits, but with incomes less than 116 percent FPL, could obtain their medications through MPAP, a Maryland Medicaid program. Medications were delivered in much the same way as under classic Medicaid, with the difference that the preferred-drug copay was $2.50, and the non-preferred-drug copay was $7.50. MPAP served around 25,000 DEs prior to January 1, 2006 (MAC 2006); as of that date, no one who is eligible for Medicare is eligible to receive the MPAP prescription-drug benefit.

Starting in 2003, Marylanders with incomes 116-174 percent FPL could obtain prescription drugs through MPDP, another Maryland Medicaid program. MPDP beneficiaries paid 65 percent of the Medicaid-established price of their medications, which is generally about 80 percent of the full retail price (Coats and Flint 2006). The program was serving about 8,000 Medicare enrollees prior to January 1, 2006 (FPIS 2005); as of that date, no one who is eligible for Medicare is eligible to receive the Medicaid prescription-drug benefit.

In addition to the above Medicaid-administered programs, two non-Medicaid programs also assisted some lower-income Marylanders with prescription drug costs prior to January 1, 2006: the Senior Prescription Drug Program (SPDP), now defunct, and Medbank. Neither program seems likely to have been the source of long-term assistance to PLWH/As in obtaining HIV medications.

SPDP was available to Medicare beneficiaries with incomes less than 300 percent of poverty. There was a $10 monthly premium and varying levels of copays; annual benefits were capped at $1,100. Prior to January 1, 2006, the program served about 33,00 Medicare beneficiaries. The program ended in 2005 (FPIS 2005).

Medbank is a non-profit organization that exists to connect the un- or underinsured with programs through which drug manufacturers provide medications directly to low-income consumers, usually at no cost. Consumers can also access these programs directly. In Maryland, prior to

January 1, 2006, Medbank was serving about 27,000 people (FPIS 2005).

Warned by the CMS inspector general that continuing to offer free or discounted prescriptions to Medicare-eligible persons may violate federal anti-kickback laws, most drug manufacturers will no longer offer these programs to the elderly or disabled. As a result, Medbank stopped processing applications of Medicare-eligible individuals as of January 1, 2006. It is doubtful that this affects patients who are receiving ongoing regimens of HIV medications: according to Nancy Forno, Medbank's operations manager, Medbank generally facilitated only one-time fills of HIV medications before referring recipients to MADAP (Forno 2006). In other words, this change is not likely to have left un- or underinsured PLWH/As in any worse straits than before.

Table 10

Pre-Part D Prescription-Drug Programs in Maryland

Program	***Income Level***	***Cost Sharing***
Medicaid Programs	<135% FPL (and non-DEs up to 175% FPL)	Varies by program
Maryland Medical Assistance (Medicaid)	<75% FPL	*Premium*: $0 *Deductible*: $0 *Copays*: • $2 brand • $0 generic
Maryland Pharmacy Assistance Program	<116% FPL	*Premium*: $0 *Deductible*: $0 *Copays*: • $7.50 brand • $2.50 generic
Maryland Prescription Drug Program	<175% FPL (including non-DEs earning 135% FPL and up)	*Premium*: $0 *Deductible*: $0 *Copays*: • 65% retail cost after Medicaid discount • $1 processing fee per scrip
Non-Medicaid Programs		
Medbank	<200% FPL	$0-$10 copays
Senior Prescription Drug Program	<300% FPL	*Premium: $10* *Deductible: $0* *Copays:* • $35 non-preferred • $20 preferred • $10 generic ($1,000 cap)

Source: MMAP 2004

4.1.1.2 FBDEs: Shifting from Medicaid to Part D

As shown in table 11, FBDEs — the poorest DEs — will see only minor differences between their old and new coverage, assuming that they are easily able to obtain needed medications through their PDP (an assumption that may not hold true with all PDPs, for the reasons described in section 3.2.2).

Table 11

FBDEs: Transitioning from Medicaid to Medicare Part D

State Programs (pre-Part D)			***Medicare Part D***			***Estimated Impact of Change for PLWH/As****	
Income Level	*State Program*	*Cost Sharing*	*Income Level*	*Donut Hole?*	*Cost Sharing*	*Pre-Part D Costs*	*Part D Costs*
< 75% FPL	Maryland Medical Assistance (Medicaid) *Premium*: $0 *Deductible*: $0	*Copays*: • $2 brand • $0 generic	<100% FPL	No	*Premium*: $0 *Deductible*: $0 *Copays*: • $3 brand • $1 generic (Above $5,100, copays=$0)	Up to $96/year	Up to $36/year

* These calculations assume an average of 4 brand-name prescriptions per month for 12 months, and assume that the cost for those medications exceeds $5,100 every 3 months, as is the case with the average MADAP client.

Source: MMAP 2004, Anders 2005

FBDEs have incomes less than 75 percent FPL. Prior to January 1, 2006, FBDEs were eligible to receive prescription drugs under Maryland Medical Assistance (Medicaid) through a fee-for-service system, in which clients generally received whatever drugs their physician prescribed (MMAP 2004). There were no premiums or deductibles; the only expense was the $2 copay required for name-brand medications. Assuming that PLWH/As in this program were on HIV-medication regimens similar to those of the state's MADAP clients, annual client costs under this program could have been as high as $96 (an average of four prescriptions per month for 12 months, assuming all were brand-name), although this entire cost would have been waivable at the pharmacist's discretion (Anders 2005).

Under Part D, FBDEs are eligible for the LIFS level of extra help, meaning that they incur no costs for covered drugs other than copays ($1 for generic-brand medications and $3 for name-brand medications), which they pay only until the total annual cost of their prescriptions exceeds $5,100. Assuming that FBDE PLWH/As with Part D benefits will be on HIV-medication regimens similar to those of the state's MADAP clients, these clients are likely to achieve catastrophic coverage within the first three months of a given year, having paid no more than about $36 in total, annual out-of-pocket expenses (Anders 2005).

In short, the impact on FBDEs of switching from Maryland Medicaid into Medicare Part D is negligible for some and a marked improvement for others, assuming that these PBDEs will be able to easily obtain prescribed medications (an assumption that may not hold true with all PDPs).

4.1.1.3 PBDEs: From Maryland Pharmacy Programs to Medicare Part D

Like FBDEs, some PBDEs will see relatively small differences between the costs of their old and new benefits, while some will see marked improvements, assuming — in both cases — that they are easily able to obtain needed medications through their PDP (an assumption that may not hold true with all PDPs, as described in section 3.2.2).

PBDEs are all of those DEs with incomes below 135 percent FPL, but not lower than 75 percent FPL (see table 12). When discussing the medication benefits that covered Maryland PBDEs before January 1, 2006, it is useful to distinguish between PBDEs with incomes above and below 116 percent FPL, the cutoff between eligibility for MPAP and MPDP. Those with incomes less than 116 percent FPL were eligible for MPAP, while those with incomes at 116 percent FPL and above were covered by MPDP.

Prior to January 1, 2006, PBDEs were eligible to receive prescription drugs through either MPAP (incomes 75-115 percent FPL) or MPDP (incomes 116-135 percent FPL). (In an example of one of the characteristics of a 1115 waiver program, MPDP also served non-DEs with incomes up to 175 percent FPL). Neither MPAP nor MPDP charged premiums and deductibles, only copays: $7.50 for brand-name medications and $2.50 for generic-brand medications under MPAP, and 65 percent of the Medicaid-negotiated retail price under MPDP. Assuming that PLWH/As in MPAP were on HIV-medication regimens similar to those of the state's MADAP clients, annual client costs under this program could have been as high as $360 (an average of four prescriptions per month for 12 months, assuming all were brand-name), although this entire cost would have been waivable at the pharmacist's discretion. Under MPDP, client costs might have been as high as about $13,260 (Anders 2005).[10]

Under Part D, PBDEs with incomes less than 116 percent FPL (previously served through MPAP), and PBDEs with incomes at least 116 percent FPL but less than 135 percent FPL (previously served through MPDP) are all eligible for one of Part D's two extra help low-income full subsidy categories. Those with incomes less than 100 percent FPL join the FBDEs in receiving Part D benefits with no premiums, no deductibles and copays of $1 (generics) or $3 (name brands), while those with incomes 116-134 percent FPL pay only slightly higher copays: $2 for generic-brand medications and $5 for name-brand medication (Anders 2005).

As was the case with FBDEs (and assuming, again, that PBDE PLWH/As with Part D benefits will be on HIV-medication regimens similar to those of the state's MADAP clients), PBDE PLWH/As are likely to achieve catastrophic coverage under Part D within the first three months of a given year, having paid no more than about $36 (those earning less than 100 percent FPL) or $60 (those earning less than 135 percent FPL) in total, annual out-of-pocket expenses (Anders 2005).

In short, the financial impact on PBDEs of switching from the Maryland Pharmacy Programs into Medicare Part D is negligible for some and a marked improvement for others, assuming that these PBDEs will be able to easily obtain prescribed medications (an assumption that may not hold true with all PDPs). There are some additional potential problems, however, both in terms of the statute as written and in terms of the logistical challenges of actually implementing it, as discussed in section 4.2, below.

[10] Average MADAP client costs in 2005 exceeded $5,100 every three months: $5,100 x 4 (quarters of the year) = $20,400; $20,400 x 65% = $13,260 (Anders 2005).

Table 12

PBDEs: From Pharmacy Programs to Medicare Part D

State Programs (pre-Part D)			***Medicare Part D***			***Estimated Impact of Change for PLWH/As****	
Income Level	*Program*	*Cost Sharing*	*Income Level*	*Donut Hole?*	*Cost Sharing*	*Pre-Part D*	*Part D*
<100% FPL	Maryland Pharmacy Assistance Program	*Premium*: $0 *Deductible*: $0 *Copays*: • $7.50 brand • $2.50 generic	<100% FPL	No	*Premium*: $0 *Deductible*: $0 *Copays*: • $3 brand • $1 generic (Above $5,100, copays=$0)	Up to $360/year	Up to $36/year
<116% FPL	(Same as above)	(Same as above)	<135% FPL	No	*Premium*: $0 *Deductible*: $0 *Copays*: • $5 brand • $2 generic (Above $5,100, copays=$0)	Up to $360/year	Up to $60
<135% FPL	Maryland Pharmacy Discount Program	*Premium*: $0 *Deductible*: $0 *Copays*: • 65% retail cost after Medicaid discount • $1 processing fee per scrip				Up to $13,260/ year	Up to $60

* These calculations assume an average of 4 brand-name prescriptions per month for 12 months, and assume that the cost for those medications exceeds $5,100 every 3 months, as is the case with the average MADAP client.

Source: MMAP 2004, MRC 2005b, Anders 2005

4.1.1.4 Maryland State Subsidies of Part D Costs

The above discussion of client costs under Medicare Part D was concerned entirely with those costs associated with the federal government's program, in the absence of any other financial assistance from state governments. Under CMS regulations, however, states are free to further supplement Part D costs incurred by their residents.

One means of doing so that exists specifically for this purpose is SPDAP, a program that the Medicare Modernization Act allows states to use to help moderate-income Medicare beneficiaries (i.e., those not eligible for LIFS), regardless of age, pay their Part D premiums. Maryland's SPDAP program is part of the Maryland Health Insurance Plan (MHIP), a state-run health insurance program for those with no other form of insurance, among other qualifying factors. The current benefit offered by SPDAP to Part D enrollees with incomes 135-300 percent FPL is $25 toward the monthly premium (SPDAP 2005), currently estimated to average $32.20 nationally in 2006 (MRC 2005b).

It is the Maryland AIDS Drug Assistance Program, however, that will administer most of the state's efforts to subsidize PLWH/A costs under Part D (see table 13). MADAP's goal is to work

with SPDAP to ensure that, essentially, no Maryland Part D beneficiary earning less than 500 percent FPL will incur any premium costs under Part D; MADAP will also pay these beneficiaries' leftover Part D deductible, copay and coverage-gap costs for MADAP formulary drugs.[11] Importantly, MADAP contributions toward Part D clients' coverage-gap costs do not count toward the total cost needed for the client to attain catastrophic coverage status. In other words, were MADAP to commence paying *all* of the coverage-gap costs for a given beneficiary, that beneficiary would never attain catastrophic coverage status and would remain responsible for 100 percent of the cost of any non-MADAP-formulary drug that he or she might be prescribed, until the beneficiary's total drug costs exceed $5,100.

For PLWH/A Part D beneficiaries earning less than 150 percent FPL (including all FBDEs, PBDEs, and some non-DE beneficiaries), MADAP's assistance means that *the only costs they could incur would be copays for non-MADAP-formulary drugs.* Again, PLWH/As in this category are likely to attain catastrophic coverage status within the first three months of the year, after which this category of beneficiary would no longer incur copays for any drug for the rest of the year.

PLWH/A Part D beneficiaries earning 150-500 percent FPL face the coverage gap known as the donut hole, which is to say that CMS considers them (or some other payer, such as, in this context, MADAP) responsible for 100 percent of their prescription costs from the point at which their costs exceed $2,250 to the point at which their costs exceed $5,100 (at which point they achieve catastrophic coverage status and are responsible for only 5 percent of medication costs). Absent any state help, this coverage gap would leave these beneficiaries responsible for up to $2,850, in addition to premium, deductible and copay costs. Again, MADAP (coordinating with SPDAP) will ensure that these client's premium costs are covered and will pay deductibles, coverage-gap costs and copays for MADAP-formulary drugs.

Since it is possible that a PLWH/A might be prescribed medications not on the MADAP formulary, however, the biggest risk for these clients is that this may occur while they are in the donut hole, when they would have to pay 100 percent of the cost. However, as mentioned in section 4.1.1.3, the Part D benefit — coverage gap and all — still represents an improvement in terms of costs over even the best benefit (MPDP) for which anyone in this income range would have previously qualified: under MPDP, these beneficiaries would have been responsible for 65 percent of the Medicaid-negotiated price for their prescriptions throughout the entire year.

In short, state subsidies provided through MADAP and SPDAP will have the result of eliminating the already relatively tiny copay costs for the poorest DE PLWH/As (0-135 percent FPL), while substantially decreasing the cost burden that would otherwise be shouldered by moderate-income Part D beneficiaries.

And even if MADAP and SPDAP suddenly lost their ability to offer these subsidies altogether, it would still be the case that no category of Part D beneficiary would, under Part D, incur greater drug costs than they would have incurred prior to January 1, 2006. (This is assuming that all Part D beneficiaries will be able to easily obtain all prescribed drugs, an assumption that may not hold true with all PDPs.)

[11] MADAP's formulary consists of over 100 drugs used to treat HIV or HIV-related conditions.

Table 13

Maryland Medicaid/Pharmacy Programs Compared to Medicare Part D

State Programs (pre-Part D)			***Medicare Part D***			***State Assistance***	
Income level	*State Program*	*Cost Sharing*	*Income Level*	*Donut Hole?*	*Cost Sharing*	*State Assistance*	*Remaining Annual Cost to Client*
<75% FPL (Full-benefit dual eligibles)	Maryland Medical Assistance (Medicaid)	*Premium*: $0 *Deductible*: $0 *Copays*: • $2 brand • $0 generic	<100% FPL (includes DEs)	No	*Premium*: $0 *Deductible*: $0 *Copays*: • $3 brand • $1 generic (Above $5,100, copays=$0)	None	$1/$3 copays[12] until $5,100 in med costs is reached.
<116% FPL (Partial-benefit dual eligibles)	Maryland Pharmacy Assistance Program	*Premium*: $0 *Deductible*: $0 *Copays*: • $7.50 brand • $2.50 generic	<135% FPL	No	*Premium*: $0 *Deductible*: $0 *Copays*: • $5 brand • $2 generic (Above $5,100, copays=$0)	None	$2/$5 copays[13] until $5,100 in med costs is reached.
<175% FPL (<135% FPL: partial-benefit dual eligibles)	Maryland Pharmacy Discount Program	*Premium*: $0 *Deductible*: $0 *Copays*: • 65% retail cost after Medicaid discount • $1 processing fee per scrip	<150% FPL	No	*Ann. Premium*: $0-@ $387[14] *Deductible*: $50 *Copays*: • Below $5,100, 15% of cost (up to $765) • Above $5,100, $2 gen./$5 brand	*Premium*: SPDAP[15] pays up to $300; MADAP pays rest. *Deductible/Copays*: MADAP pays these for drugs on its formulary	Deductible[16] or copays for non-MADAP-formulary drugs.
			150-300% FPL	Yes	*Ann. Premium*: @ $387[17] *Deductible*: $250 *Copays*: • 25% of the first $2,000 after initial deductible (i.e., up to $500) • 100% of next $2,850 (the donut hole) • Above $5,100, 5%	*Premium*: SPDAP pays up to $300 (on "basic"[18] plans); MADAP pays rest/"enhanced" plan. *Deductible/Copays*: MADAP pays these for drugs on its formulary *Donut Hole*: MADAP covers these costs	Deductible[19] or copays for non-MADAP-formulary drugs.
<200% FPL (exact income limits vary by manufacturer)	Medbank	None					
<300% FPL	Senior Prescription Drug Program[20]	Premium: $10/mo. Deductible: $0 Copays: • $35 non-preferred • $20 preferred • $10 generic ($1,000 cap)					
			300-500% FPL	Yes	Same as 150-300% FPL (above)	Same as 150-300% FPL (above), except not eligible for SPDAP; MADAP pays entire premium.	Deductible[21] or copays for non-MADAP-formulary drugs.

[12] An increase in costs for this category of client: Medicaid copays were waivable; these copays are not. This cost could conceivably be a Title I burden (on average, $1-$3 x @4 months [@ time needed to reach catastrophic coverage level for average HIV patient] per client), because MADAP cannot pay for someone with Medicaid.

[13] An increase in costs for this category of client: Medicaid copays were waivable; these copays are not. This cost could conceivably be a Title I burden (on average, $1-$3 x @4 months [@ time needed to reach catastrophic coverage level for average HIV patient] per client), because MADAP cannot pay for someone with Medicaid.

[14] Each plan can structure premium and other costs separately, subject to CMS's approval. CMS estimates that the national average premium cost will be $32.20 in 2006 (MRC 2005b).

[15] According to Linda Anders of MADAP, it is not yet settled how much help SPDAP will offer in total, or how it will be administered. Anders says that, for now, clients falling into this income category will apply to MADAP, where they will then be screened for eligibility for help from SPDAP. Essentially, whatever SPDAP does not cover, MADAP is pledged to cover, provided that deductibles and copays/co-insurance are paid for MADAP formulary drugs.

[16] Since most PLWH/As are on multiple medications, including MADAP-covered HIV drugs, avoiding paying this (and getting MADAP to pay it) would, in most cases, simply be a matter of the pharmacist changing or being urged to change the order in which a stack of prescriptions are being filled.

[17] Each plan can structure premium and other costs separately, subject to CMS's approval. CMS estimates that the national average premium cost will be $32.20 in 2006 (MRC 2005b).

[18] Basic plans have donut holes, as opposed to enhanced plans that defray donut hole costs, but at a higher premium. However, depending on the individual client's needs,

MADAP may counsel disregarding the potential help from SPDAP and enrolling in an enhanced plan at MADAP's expense if such a plan would ultimately better serve that client. (Otherwise, MADAP pays the donut hole costs.)

[19] Since most PLWH/As are on multiple medications, including MADAP-covered HIV drugs, avoiding paying this (and getting MADAP to pay it) would, in most cases, simply be a matter of the pharmacist changing or being urged to change the order in which a stack of prescriptions are being filled.

[20] SPDP was never available to anyone with any other form of prescription-drug coverage.

[21] Since most PLWH/As are on multiple medications, including MADAP-covered HIV drugs, avoiding paying this (and getting MADAP to pay it) would, in most cases, simply be a matter of the pharmacist changing or being urged to change the order in which a stack of prescriptions are being filled.

Source: The "State Programs and "Medicare Part D" columns of this table are adapted from a similar table prepared by Maryland's Department of Legislative Services. Other sources: MMAP 2004, MRC 2005b, Anders 2005

4.2 Summary of Problems with Part D

The rollout of the Medicare Part D benefit has not been without its problems, as even the most cursory glance at Medicare-related news makes clear. These problems can be divided into two main categories: (1) those that are inherent to Part D under the terms of either the MMA itself or CMS's regulatory interpretation of the MMA and (2) those that result from what might be called implementation glitches, i.e., situations in which Part D does not appear to be operating as designed. Though the planning council is limited in the actions it can take in response to any of these problems, this section presents a summary of some of the major, known Part D problems as an aid to understanding ongoing media coverage as well as what the Part D implementation has been like for individual beneficiaries.

4.2.1 Problems Inherent to Part D

Though the model benefit propagated by CMS may give the impression that PDPs must offer a standard, uniform benefit, CMS actually allows PDPs great leeway in deciding which drugs to cover and how to cover them. As a result, some Part D enrollees may face considerable expense (higher copays) and/or inconvenience (prior authorization requirements) before obtaining certain drugs that their physician has prescribed — even in the case of drugs that a plan specifically advertises as covered. Enrollees can request exceptions to higher copays and determinations of non-coverage, and denied exceptions can be appealed, but the process for both (1) requires the assistance of the prescribing physician, (2) varies from plan to plan, and (3) appears likely to be time consuming. Also, some of CMS's limitations on the exceptions process may discriminate against some enrollees on the basis of their medication needs, in violation of the MMA's anti-discrimination requirements.

4.2.1.1 Unsuitable Plans

Under CMS regulations, PDP drug formularies can vary widely, and some may be better suited than others for a specific beneficiary's medication needs. For example, a Connecticut study of PDPs offered in that state found that "four of the ten 'worst' plans for [a] person with schizophrenia did a better-than-average job covering the medications of [a] prototype senior" (CHF 2006:3). Except in the case of autoenrolled dual eligibles, enrolling in an unsuitable plan would be the beneficiary's mistake, of course. But given the many plans available (over 40 in Maryland) and anecdotal evidence of plans and CMS itself publishing inaccurate drug and price data (Wolfe 2005, MRC 2005a), it would be an easy mistake to make.

Psychologist Barry Schwartz, citing "modern research in the psychology of decision making," explains that, even in the case of "extremely consequential choices…when you increase choice by offering more and more options, a point is reached at which paralysis rather than 'freedom' is the result." CMS's recent proposal to start limiting the number of drug plans a company may offer

suggests that the agency may have come to the belated conclusion that there is such a thing as too much choice (Frekin 2006). Schwartz predicts that, "[t]o simplify a hopelessly complex task, people may choose solely on the basis of price (take the cheapest) or on the basis of brand (choose a plan offered by a company you've heard of)," as opposed to carefully considering the nature of the coverage or the consequences of remaining uncovered (Schwartz 2005). But the PDPs that appear to be the cheapest "may be the most costly in reality…because some plans with high premiums provide discounted drug coverage even within the doughnut hole [coverage gap]" (Hiltzik 2006).[22]

Of course, for the many DEs whom CMS autoenrolled into "randomly assigned" PDP plans on January 1 (HHS 2006:ii), there was no choice at all (although DEs were allowed to opt out of this process and choose their own plans). The results, reported January 27, 2006 by HHS's inspector general, are striking: "[a]lmost one-third of dual eligibles (30 percent) are assigned to plans that include less than 85 percent (151 or fewer) of the 178 most commonly used drugs" by Medicare beneficiaries (HHS 2006:ii).[23] CMS objected to this method of analysis, saying it was more important to look at whether enrollees have access to their prescribed medications (rather than "commonly used drugs"). However, by CMS's own admission, "8.2 percent [of DEs] were assigned to plans that covered less than 70 percent of [those enrollees' prescribed] drugs" nationwide (Appleby and Wolf 2006). In the PDP region that consists of Maryland, Delaware and Washington, D.C., only 14 percent of autoenrolled beneficiaries are in plans covering 100 percent of the commonly used drugs, while 21 percent are in plans that cover less than 85 percent of commonly used drugs (HHS 2006:36).

4.2.1.2 Covered Drugs May Not Be Easily Obtainable

Even if Part D enrollees pick the plan that is best suited to their individual prescription needs, they still cannot be certain that they will be able to get a drug their doctor prescribes simply by presenting their prescription at a pharmacy. For DEs, difficulties obtaining a prescription immediately may be markedly different from their experience under Medicaid. A *Los Angeles Times* health columnist lays out the dimensions of the problem:

- At the PDP's discretion, enrollees may only get a drug from the same "class" of drugs as the drug their doctor prescribes. PDPs face market incentives to minimize their costs, and "[h]ealthcare professionals expect the plans to exploit their power over formularies very aggressively to keep costs controlled" (Hiltzik 2006).[24]
- "The plans also are permitted to impose stringent prior-authorization rules almost at will. These typically force doctors to jump through hoops — such as filling out paperwork or spending hours on the phone with health plan reps drilled in how to say "no" — before a plan will pay for a prescribed medicine, even if it's on the formulary" (Hiltzik 2006).[25]
- Also, "the health plans are permitted to drop drugs from their formularies at any time with 60 days' notice; [non-DE] patients, however, are only permitted to change plans once, at the end

[22] DEs do not face the donut hole coverage gap.
[23] The 21 most commonly omitted drugs, missing from over one quarter of all PDP formularies, are brand-name medications without generic equivalents and include drugs for the treatment of high blood pressure, cholesterol and pain (HHS 2006, p. 12).
[24] *Newsday* reported one instance in which a patient who had been receiving a name-brand anti-psychotic became psychotic after his PDP switched him to a generic version of the drug (Ochs 2006).
[25] *Newsday* reported one instance in which a PDP required a sample of a patient's infected toenail before granting prior authorization for an internal antifungal drug (Ochs 2006).

> of the year.[26] Therefore, although enrollees will choose plans based on the drugs covered, they may find one or more dropped from the lists as the year wears on…[and] may end up paying full price for drugs they thought would be covered"[27] (Hiltzik 2006).

Finally, a PDP might "cover" a certain drug only in a specific dosage or form, meaning that one enrollee's prescription for a liquid form of a drug may be filled upon presentation at a pharmacy, while another enrollee's prescription for the same drug in pill form could be denied (KFF 2005c: 6).

4.2.1.3 Arduous Exceptions and Appeals Processes

As described above, there are multiple scenarios in which Part D PDP enrollees may be prescribed a drug that their PDPs either do not cover, do not cover in the prescribed form or cover at a higher cost-sharing rate than other covered drugs. To obtain a non-covered drug, or to get a covered drug under more favorable cost sharing, beneficiaries must follow their plan's exceptions-and-appeals process. An exception is an enrollee's first request that a non-preferred drug be made available or that cost sharing be modified. An appeal is an enrollee's request that a denied exception be reconsidered.

In 2005, KFF analyzed CMS's rules regarding exceptions and appeals processes. KFF found that CMS's rules may result in processes that are unwieldy and arduous for both enrollees and their physicians, and that may discriminate against some enrollees.

Exceptions and appeals processes may be frustrating and time consuming. For example, neither exceptions nor appeals can be granted unless supported by a statement from the prescribing physician, but each PDP sponsor may impose different requirements as to the format and contents of this statement. "Thus, physicians with patients enrolled in the broad array of drug plans available in their community may have to familiarize themselves with over 40 different exceptions processes…[which] may result in barriers to effective assistance by physicians" (KFF 2005c:13).

And even physicians who successfully assist enrollees in mounting exceptions or appeals may find themselves doing so again and again: plans "are only obligated to abide by [their exceptions and appeals] decisions through the end of the year," so beneficiaries and their physicians may have to repeat the process on an annual basis. "Such a policy may dissuade an individual from remaining in a plan and could potentially be used to encourage enrollees with more costly drug requirements to choose a different plan," an inconvenience for the enrollee as well as a violation of the MMA's anti-discrimination requirements (KFF 2005c:13).

Enrollees may also find themselves effectively pushed out of their PDP as a result of certain limitations imposed by CMS regulations — over and above the requirements of the MMA — on the exceptions and appeals process. These limit exceptions and appeals for changes in cost sharing in a way that could essentially "penalize [some beneficiaries] based on their medical condition or illness, in contradiction of the anti-discrimination requirements in the statute" (KFF 2005c:13).

Problems with the exceptions-and-appeals process could have a significant impact on enrollees, not only because of the multiple scenarios described earlier, under which enrollees might need to

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[26] DEs may change plans once a month, however, the logistical problems and administrative delays that might reasonably be expected to accompany such a switch may lead many beneficiaries to consider this option as a last-resort fallback.

[27] In Maryland, MADAP will cover any cost for any drug on its formulary for its clients (incomes less than 500 percent FPL) (Anders 2005).

access a non-covered or more expensive drug, but because of the fact that the number of drugs for which such processes are necessary is likely to increase over time. This would happen if PDPs decreased the number of drugs on their formularies, for example, or "assign[ed] more drugs to higher cost-sharing tiers" (KFF 2005c:13). One reason PDPs might take such actions would be if overall enrollment, already anemic, remains below predicted levels (Haase 2006). Another reason for such aggressive cost-containment actions by PDPs would be if only the sickest Medicare eligibles enroll, which so far seems likely to be the case (PRN 2006).[28]

4.2.2 Part D Implementation Glitches

As opposed to problems inherent to the statute as written, there are also turning out to be significant implementation glitches and other obstacles preventing many beneficiaries, especially DEs, from obtaining Part D coverage and "extra help" subsidies, and CMS's effort to publicize Part D-related information has been characterized by a high level of errors and inaccuracies. Reports in the media, as well as from advocacy and watchdog groups, show that most PDPs disregarded CMS rules regarding transition policies designed to prevent interruptions in enrollees' drug regimens. Also, despite CMS's claim to have "developed a…point-of-sale [system] to ensure [that] full dual-eligible individuals experience no coverage gap when Part D coverage commences," widespread problems with PDP and CMS information systems have prevented "hundreds of thousands" of enrollees — including 200,000 DEs in California alone — from obtaining coverage and/or subsidies (CMS 2005a:1; Pear 2006a).

4.2.2.1 CMS Published Inaccurate Information

In the months leading up to January 1, 2006, accusations of inaccurate and misleading information swirled around CMS and two of its Part D information-delivery portals, the web site medicare.gov and the helpline 1-800-Medicare. Senator Olympia Snowe (R-Maine) publicized the case of one constituent who found a $2,000 price difference between PDP information provided on CMS's web site and that provided by the PDP itself, and CMS admitted in December 2005 that a great deal of the information available through the site was flawed (MRC 2005a). The help available at 1-800-Medicare was no better: the Government Accountability Office (GAO) found that "the accuracy rate for [the helpline] was a mere 61 percent prior to the implementation of Medicare Part D" (MRC 2005a).

4.2.2.2 Transition Plans Not Publicized

Any prescription-drug plan of Part D's size and scope can reasonably be expected to experience some glitches in the early stages of rollout. In the interest of preventing such glitches from interrupting enrollees' vital treatment regimens, CMS required all PDPs to formulate transition plans that would include procedures for delivering at least an initial supply of any medications that an enrollee was already receiving, even if those medications were not technically covered by that PDP, or required prior authorization, or were affected by other plan-specific restrictions (CMS 2005a:4).

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[28] A national survey of seniors in December found that, while over 73 percent of seniors surveyed said they were "somewhat or very familiar" with Part D, 53 percent of seniors surveyed said they are neither enrolled nor intend to enroll in a Part D plan. This same 53 percent took the fewest drugs, spent the least on their prescriptions, and made the fewest doctor and hospital visits. In other words, out of all possible Medicare eligibles, there is reason to suspect that the population likely to join Part D plans will be generally more expensive for those plans to cover (PRN 2006).

A CMS document entitled "Information for Part D Sponsors on Requirements for a Transition Process" states that "plan sponsors must make transition process [policies] available to beneficiaries in a manner similar to information provided on formularies and benefit design" (CMS 2005a:4), so that beneficiaries could take such information into account before selecting a PDP. As late as December 2005, however, "few" drug plans had complied with this directive and others had publicized plans that did not satisfy CMS requirements, according to the Medicare Rights Center, a non-profit advocacy group (MRC 2005a). By mid-January, it was clear that many PDPs were failing to provide CMS's minimum required transition assistance, leaving seriously ill people cut off from medications and moving the White House to issue an across-the-board order requiring PDP sponsors "to provide a 30-day supply of any drug that a beneficiary was previously taking," as reported by the *New York Times* (Pear 2006a). This was at the same time that about 20 states, concerned by reports of massive numbers of the poorest and sickest beneficiaries unable to obtain vital prescriptions, instituted emergency measures to pay for drugs that should have been covered by PDPs or provided under transition plans; four states declared official public health emergencies. As one example of the extent of the problem, one of these states — Maine — incurred about $2 million in drug costs for Medicare beneficiaries in less than one week (Pear 2006b).

4.2.2.3 Incorrect Enrollment and "Extra Help" Information

Problems with PDP transition policies were not the only reason that so many beneficiaries were prevented from obtaining prescriptions: many people who were enrolled in PDPs did not show up in those PDPs' records when pharmacists attempted to verify membership, and many people whom CMS had approved for an extra help subsidy were told that they had to pay full price.

One problem affected DEs specifically. As mentioned earlier, DEs who did not pick their own PDP were to be autoenrolled into a PDP on January 1, 2006, although they were also allowed to opt out of this process by choosing their own PDP ahead of time. However, according to *Forbes*, those who did so typically lost their designation as eligible for "extra help" in CMS's records (Forbes 2006). Without extra help, Part D enrollees are responsible for the first $250 in their drug costs, a far cry from the $1-$5 copay that should have been DEs' only cost. Other information-system problems were rampant. For example, some DE and non-DE enrollees did not show up as enrolled on PDP computer systems accessed by pharmacists; other computer systems were so overwhelmed by queries that they crashed (MRC 2006b). The usual procedure in such cases would be for the pharmacist to then contact the PDP by phone, but the massive volume of calls being received by many PDPs made this an unwieldy alternative, to say the least. Numerous media sources reported pharmacists waiting on hold for hours at a time to verify enrollment for a single beneficiary (MRC 2006a). Finally, enrollment into the SSA-administered "extra help" subsidy program does not appear to be going well. According to analysis by MRC, as of February 16, 2006, "the Social Security Administration [had] enrolled only 1.1 million low-income older Americans and people with disabilities out of an estimated 8.2 million [people] potentially eligible" for extra help (MRC 2006c).

4.2.2.4 Small Pharmacies Negatively Affected

As reported in *Newsday*, the "head of the Society of Pharmacists for New York State predicted about 200 pharmacies in the state — hit by lower reimbursements, employee overtime and the cost of medications they have given away [rather than deny patients vital medications due to apparent glitches and errors by CMS, CMS contractors and PDPs], will go out of business in the next few months" (OCHS 2006). A prognosis for Maryland's small pharmacies had not been located at press time.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusion

Medicare Part D is a voluntary prescription-drug benefit available to anyone who is eligible for Medicare. In addition to senior citizens, eligibility extends to disabled Medicaid recipients, known as "dual eligibles" (DEs) because they may participate in both programs. There are about 94,000 DEs in Maryland, including at least 1,100 PLWH/A DEs in the Baltimore EMA.

Under Part D, private companies and nonprofit organizations offer PDPs that operate similarly to other forms of health insurance, with premiums, deductibles and copays. There is an "extra help" subsidy, paid on behalf of lower-income enrollees by SSA, that eliminates almost all costs for DEs and many costs for slightly higher-income beneficiaries.

Part D is designed with great deference to the PDP sponsors, with no requirement that they deliver a uniform, standard benefit. Within certain limitations, PDPs have wide latitude in determining which drugs they will cover and how they will structure cost sharing. While CMS has propagated a "model benefit" that shows what coverage might look like — in terms of costs and coverage gaps — PDPs are only obligated to deliver a benefit of equivalent value to the model benefit. In practice, this means that enrollees could encounter cost sharing for certain drugs that greatly exceeds what the model benefit leads them to expect.

And while CMS requires PDPs to cover all medically necessary drugs, this requirement is defined by CMS in a way that allows PDPs to make substitutions or require step therapy or prior authorization from prescribing physicians, even for drugs that may have been advertised as covered. As a result, it is by no means guaranteed that enrollees can depend on accessing all drugs prescribed to them, although estimating the precise extent of this possibility would be a massive undertaking requiring close analysis of the more than 40 PDPs offered in Maryland.

Assuming for the sake of argument that most enrollees will be able to access most needed prescriptions, whether initially or through the exceptions and appeals processes that CMS requires all PDPs to offer, it is possible to make several broad statements about the effects of Part D (based on CMS's model benefit):

- Part D is only a minor change for DEs; because of the extra help subsidy, Part D offers a benefit that is not any more expensive than Medicaid's drug benefit was.
- Part D is a significant improvement for slightly higher-income Marylanders; before Part D, these would only have been eligible for help with their drugs from MPDP, which required much higher copays than does the Part D model benefit.
- Part D offers a drug benefit for other non-DEs who never before had access to a particularly robust public drug benefit.

In Maryland, additional subsidies offered by MADAP and SPDAP essentially eliminate all leftover costs for PLWH/As with incomes 135-500 percent FPL, except for cost sharing on drugs that are not on the MADAP formulary.

But any positive conclusions about Part D in the abstract must be tempered with concern about the many potential problems inherent both to the MMA and to CMS's regulations as written, as well as the significant number of technical glitches, missteps and non-compliance with regulations that have attended the rollout. Problems inherent to the program as designed include

the PDPs' great flexibility in deciding which drugs to cover and how to structure cost sharing; potentially arduous exceptions and appeals processes; and elastic use of the term "covered drugs."

Implementation glitches include dissemination of inaccurate coverage and cost information by both CMS and individual PDPs; CMS's failure to properly process and handle the records of hundreds of thousands of enrollees, resulting in denial of coverage and/or "extra help" subsidies; inadequate preparation for high volumes of traffic on CMS and PDP computer and helpline systems, resulting in system crashes and inordinately long hold times for pharmacists verifying enrollment information; and non-compliance by most PDPs with CMS's directive that they publicize their plans for avoiding interruptions in the existing drug regimens of new enrollees ("transition plans"). Also, drug manufacturers were recently warned by the inspector general of the U.S. Department of Health and Human Services that programs offering free medications to low-income clients may violate federal anti-kickback laws; as a result, most manufacturers are discontinuing these programs.

In addition, initial enrollment has been lower than expected, and there is reason to suspect that it is the sickest, poorest Medicare eligibles who are most likely to sign up for the program. If so, it is possible that some companies will lose interest in sponsoring Part D PDPs, while others may shrink their formularies and increase cost sharing, with negative effects on lower-income beneficiaries.

Medicare Part D, then, represents a massive change in the structure of health-care delivery in this country and in the state of Maryland. While the poorest beneficiaries seem relatively well-protected from the worst of the potential problems inherent to the benefit, the bungled rollout does not bode well for the continued health of the program and indicates a need for continued close monitoring.

5.2 Recommendations and Cautions

Even at this late date, it is not certain how the Medicare Part D prescription-drug benefit will affect each individual enrollee or the continuum of HIV care in the Baltimore EMA. If it were the case that all Part D enrollees could easily obtain all prescribed medications (as would essentially have been the case for Maryland DEs prior to Part D, through Medicaid), then it would be safe to say that the approximately 1,100 HIV-positive DEs in the Baltimore EMA would not be much affected by the change at all.

However, as described in this report, it is by no means the case that all Part D enrollees will be able to obtain all needed medications, even assuming that the program is functioning as designed: the wide variability among PDPs makes it possible for the benefit to be a great boon for some enrollees and frustrating and expensive for others, with inaccurate and misleading marketing information being propagated by both CMS and individual PDP sponsors.

And of course Part D is not functioning as designed: hundreds of thousands of Part D enrollees across the country — including many DEs — are experiencing serious difficulties obtaining both their prescriptions and the extra help subsidy that makes it possible for them to afford these drugs — even enrollees who have followed CMS instructions and timetables to the letter.

This section explains three recommended planning council responses to Part D, in addition to explaining why several other tempting courses of action may not be appropriate for the planning council.

5.2.1 Recommendations

Planning council members who are concerned by the many potential problems with Part D may wonder how — if at all — the planning council should respond. As troubling as Part D's intended and unintended consequences may be, the planning council is limited both by statute and by best policy-making practices as to what actions it should consider taking.

5.2.1.1 Establish ADAP

As explained earlier in this report, a great deal of assistance with individual beneficiaries' Part D costs will be provided by MADAP: working with SPDAP, MADAP intends to eliminate virtually all costs that PLWH/As with incomes under 500 percent FPL might incur under Part D. This includes payment of premiums not covered by any other assistance program, as well as deductibles and cost sharing (i.e., copays, or even full price for a non-covered drug) for MADAP-formulary drugs. This safety net greatly increases the chance that no DE will incur greater expenses under Part D than under Medicaid, at the same time that it extends low-cost drug coverage to more people than previously enjoyed a public drug benefit in Maryland.

In light of CMS's sub-par performance thus far — as well as the possibility that Part D benefits may contract if enrollment remains low or continues to over-represent sicker Medicare beneficiaries — the planning council should consider what it will do in the event that MADAP becomes less able to subsidize the Part D benefit for Maryland's PLWH/As. If this happens, the main impact will be on people with incomes 135-500 percent FPL. Of that group, only those with incomes 135-175 percent FPL would have been accustomed to receiving a medication benefit before (through MPDP), and Part D — even unsubsidized by the state — would still be less expensive for them than MPDP had been. (This is assuming that these beneficiaries will be able to easily obtain needed prescriptions, an assumption that may not hold true for all PDPs.) In other words, under the current Part D program, *MADAP's withdrawal of subsidies would not expose most people to higher costs than they would have incurred prior to Part D*.

If a circumstance arose in which the planning council decided to help MADAP subsidize Part D benefits for EMA PLWH/As, the best way for it do so would be through the AIDS Drug Assistance Program (ADAP) service category, a category that is not currently included in this planning council's list of established, ranked service categories. Since, according to the CARE Act, categories that do not appear on this list cannot be considered for possible funding, the planning council may wish establish the ADAP category for fiscal year 2007 and subsequent years.[29]

It is not necessary to actually fund the ADAP category — in fact, as things currently stand, there is no good reason to do so — since simply establishing and ranking it gives the planning council the flexibility to contribute toward MADAP's costs in an emergency at any point during the year.

5.2.1.2 Monitor Guidance from the AA and Grantee Concerning Paying Part D Costs

CMS has as yet issued no guidance to Ryan White Title I providers regarding requirements related to paying Ryan White clients' Part D costs, such as through emergency financial assistance (EFA) vouchers (Brisueno 2006). ADAPs and some other third-party payers covering Part D costs for individual beneficiaries have been notified by CMS of strict reporting requirements and must track detailed information concerning each payment, such as the exact amount paid, the drug code and the pharmacy where the prescription was obtained. However,

[29] See section 2602(b)4(c) of the Ryan White CARE Act; also, pp. 5-6 of the 2006 Priority Setting Training Manual.

CMS has not yet announced whether or not these requirements will apply to Ryan White Title I providers.

According to Ralph Brisueno, assistant director of the Ryan White Title I program at the Baltimore City Health Department (BCHD), his office — i.e., the grantee — is actively researching this matter and will issue specific reporting requirements to Title I providers as these requirements are released by CMS or HRSA. Title I providers do not need to change current operating procedures related to EFA and other payments until notified otherwise by the grantee (Brisueno 2006). As such, the planning council does not need to make any specific directives concerning this issue, but should closely monitor ongoing developments, including requesting updates from the administrative agent.

5.2.1.3 Communicate with MADAP

Also related to the first recommendation, the planning council should open and maintain a formal channel of communication with MADAP for the purpose of monitoring MADAP's experience assisting with Part D costs. Of particular interest would be any unexpected problems MADAP encounters, such as needing to help a larger number of people than anticipated, as well as MADAP's estimation of its own ability to continue offering this service. Since such a report would be at MADAP's option, the planning council should make every effort to minimize the extra work that would be involved in making such a report, such as requesting it only quarterly or semi-annually.

5.2.2 Cautions

Planning council members may be gravely concerned by some of the problems with Part D outlined in this report. In particular, the prospect of individual PLWH/As being turned away from pharmacies without life-saving medications is troubling. The question may arise as to whether the planning council should offer some form of financial assistance in such situations. Also, given the confusing variety of PDPs on the market, and the vital importance of selecting the right plan, should Title I case managers be trained in helping their clients enroll in and/or navigate the requirements of a particular plan? Once enrolled in a plan, should a beneficiary be able to turn to his or her case manager for expert help with specific exceptions or appeals processes? If the answer is yes to either of these questions, of course, additional funding for the case management service category would probably be necessary, in order to pay for Part D training.

As tempting as these actions may be, however, the planning council should probably not consider either paying enrollees' out-of-pocket costs or funding Part D training for Title I case managers, as described in more detail below.

5.2.2.1 Part D Out-of-Pocket Costs

It is *not* recommended that the planning council consider using Title I funds for the purchase of medications on behalf of PLWH/A Part D beneficiaries who are denied coverage or favorable cost sharing for a certain drug by their PDPs. Even if there were no logistical obstacles to doing so (such as the potential ones described in section 5.2.1.2), the likelihood seems strong that the existence of such an option might predispose case managers and other parties assisting clients with Part D to rely on such help rather than aggressively prosecuting what appears likely to be a lengthy and arduous appeals process. If this practice becomes widespread, a relatively large chunk of Title I funds may end up being spent on medication costs for a relatively small population of clients.

Also, as HRSA explained in a December letter to Title I directors and planning council chairs, paying Part D enrollees' cost sharing exposes the planning council to "numerous administrative and operational challenges" (see section 5.2.1.2). HRSA points out that "CARE Act payments cannot be made directly to clients for Part D," which means that payments would instead have to be directed to individual PDPs. As of November 13, there were over 40 PDPs offered in Maryland, each one of which might require a different payment process. Another reason not to consider this option is that it might seriously complicate MADAP's efforts to provide essentially the same service, "since ADAP programs must assess and compare the costs of providing medications through a health insurance option (such as Part D) versus ADAP" by considering and monitoring all other available sources of funding (HRSA 2005).

HRSA's guidance to Title I directors and planning council chairs is identical to that offered in section 5.2.1.2, above: "Part D-Care Act coordination will generally be handled best at the state level through Title II…[f]or most EMAs, it will probably be more cost-effective and less cumbersome administratively to contribute to your state's ADAP" (HRSA 2005).

5.2.2.2 Training Title I Case Managers in Part D Plan Details

It is *not* recommended that the planning council consider devoting Title I funds to providing training for case managers in the enrollment, exceptions and appeals processes for specific PDPs. It is not clear that such training is practical, given the potentially large investments of time and money that would be needed to design and deliver such training. Also, any training programs developed and delivered could quickly become obsolete, since there is nothing preventing PDPs from making frequent changes to their plans' details.

For guidance on how case managers should estimate their responsibilities for helping clients with Part D, it makes sense to consider what other health-care professionals are doing. In a recent opinion piece in the journal *Family Practice Management*, and reprinted on Medscape, the "professional portal" of the mainstream medical website WebMD, a medical doctor advised her colleagues on what she understands to be the extent of their obligations to their patients concerning Part D: "Though your patients may ask for your assistance in choosing a plan, CMS does not expect physicians to have the time or training to do this…[and instead] depends on its own staff and partner organizations for outreach, education and enrollment" (Biola 2006).

Case managers should of course be familiar with the basic outline of Part D, such as who is eligible, sources of information concerning PDPs available in Maryland (such as Medicare.gov), how to apply for "extra help," and so on. In Maryland, all PLWH/As who may be eligible for Part D should first contact MADAP. MADAP does plan to offer specific advice concerning PDPs, even going so far as to recommend enrollment in one PDP over another due to more favorable cost sharing and drug coverage (Anders and Flint 2005).

5.2.2.3 Possible Non-Planning Council Actions

Individual planning council members who wish to contribute to improving the Part D benefit may want to monitor ongoing implementation problems for specific populations and join other concerned citizens in pointing out shortcomings of and recommending improvements to Part D. Though the media are following many of the problems facing Part D beneficiaries, these problems are so numerous and complex that it may be difficult for the general public to understand exactly how certain populations, such as low-income PLWH/As, are being affected. Planning council members may be in a unique position to help monitor the situation as it unfolds and to voice concerns through newspaper op-eds, petitions and conversations with elected officials.

One way to help would be to join the efforts of various organizations that are trying to correct Part D problems. One of these, the non-profit Medicare Rights Center, is currently collecting reports of individual enrollees' problems obtaining prescriptions through Part D to help MRC's efforts to "push for a decent Medicare drug benefit"; individual stories may be submitted at www.medicarerights.org/partdstories.html. MRC's Paul Precht, an MRC policy coordinator, is also researching specific problems faced by PLWH/As under Part D. Mr. Precht may be contacted through the MRC website, www.medicarerights.org.

6. Appendices

6.1 Acronym Key

ACEP: Annual coordinated election period.

ADAP: AIDS Drug Assistance Program.

ARV: Anti-retroviral drug.

BCHD: Baltimore City Health Department.

CMS: U.S. Centers for Medicare and Medicaid Services.

DE: Dual eligible.

DHMH: Maryland Department of Health and Mental Hygiene.

EFA: Emergency financial assistance.

EMA: Eligible metropolitan area.

FBDE: Full-benefit dual eligible.

FPL: Federal poverty level.

HHS: U.S. Department of Health and Human Services.

HMO: Health maintenance organization.

HRSA: U.S. Health Resources and Services Administration.

IGS: InterGroup Services, Inc.

LIFS: Low-income full subsidy.

LIPS: Low-income partial subsidy.

MADAP: Maryland AIDS Drug Assistance Program.

MCO: Managed care organization.

MHIP: Maryland Health Insurance Program.

MMA: Medicare Modernization and Improvement Act of 2003.

MPDP: Maryland Pharmacy Discount Program.

MRC: Medicare Rights Center.

PBDE: Partial-benefit dual eligible.

PDL: Preferred drug list.

PDP: Prescription drug plan.

PLWH/A: Person living with HIV/AIDS.

RWCA: Ryan White CARE Act.

SPDAP: Senior Prescription Drug Assistance Program.

SPDP: Senior Prescription Drug Program.

SSA: Social Security Administration.

SSI: Social Security Income.

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