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Medicare Part D Prescription Drug Benefit: A Primer

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Abstract. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L.108-173) established a new voluntary prescription drug benefit under a new Medicare Part D, effective January 1, 2006. Prescription drug coverage is provided through private prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. Beneficiaries must enroll in one of these private plans in order to obtain their drug benefits. The program relies on these private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies covering the bulk of the risk are provided to encourage participation.

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Prepared for Members and Committees of Congress

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Summary

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) established a new voluntary prescription drug benefit under a new Medicare Part D, effective January 1, 2006. Prescription drug coverage is provided through private prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. Beneficiaries must enroll in one of these private plans in order to obtain their drug benefits. The program relies on these private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies covering the bulk of the risk are provided to encourage participation.

At a minimum, plans offer "standard coverage" or alternative coverage with actuarially equivalent benefits. They may also offer enhanced benefits. All plans are required to meet certain minimum requirements, including those related to beneficiary protections. However, there are significant differences among plans in terms of benefit design, drugs included on plan formularies (i.e., list of covered drugs), cost-sharing applicable for particular drugs, and monthly premiums.

In general, beneficiaries can enroll in a plan, or change plan enrollment, when they first become eligible for Medicare or during the annual open enrollment period. The open enrollment period for 2008 was from November 15, 2007, to December 31, 2007. Plans can change from year to year. Beneficiary needs may also change. Therefore, beneficiaries should review their plan choice annually to make sure that their chosen plan continues to meet their needs.

As of January 2008, approximately 25.4 million Medicare beneficiaries were enrolled in PDP and MA-PD plans. Of these, approximately 9.4 million were receiving low-income subsidy assistance. An additional 6.7 million beneficiaries had prescription drug coverage through a former employer that is receiving a federal subsidy for a portion of such coverage. Approximately 7.5 million beneficiaries had drug coverage through another source. An estimated 4.6 million or 10.4% of Medicare beneficiaries had no drug coverage.

A major focus of the drug benefit is the enhanced coverage provided to low-income individuals who enroll in Part D. Low-income enrollees, including persons (known as "dual eligibles" — those persons enrolled in both Medicare and Medicaid) who previously received drug benefits under Medicaid, have their prescription drug costs paid under Part D. Persons with incomes below 150% of poverty have assistance with some portion of their premium and cost-sharing charges. Persons with the lowest incomes have the highest level of benefits. Dual-eligibles, as well as certain other low-income enrollees, are enrolled in plans with premiums at or below the low-income subsidy level for the region. They pay a zero premium for such plans (though they may select a plan with a higher premium and pay the difference). Some plans with premiums below the low-income subsidy level in 2007 no longer qualified as zero premium plans in 2008. As a result, effective January 1, 2008, 1.6 million beneficiaries were assigned to a new plan with a new organization, and an additional 965,000 were assigned to a new plan with their existing organization. This report will be updated as events warrant.

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Overview

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L.108-173) established a new voluntary prescription drug benefit under a new Medicare Part D. The new benefit was effective January 1, 2006. Prescription drug coverage is provided through private prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. At a minimum, these plans offer "standard coverage" or alternative coverage with actuarially equivalent benefits. Beneficiaries are required to enroll in one of these private plans in order to obtain their drug benefits. The program relies on these private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies covering the bulk of the risk is provided to encourage participation.

Unlike other Medicare services, the benefits can only be obtained through private plans. Further, while all plans have to meet certain minimum requirements, there are significant differences among them in terms of benefit design, drugs included on plan formularies (i.e., list of covered drugs) and cost-sharing applicable for particular drugs.

A major focus of the drug benefit is the enhanced coverage provided to low-income individuals who enroll in Part D. Low-income enrollees, including persons (known as "dual eligibles" — those persons enrolled in both Medicare and Medicaid) who previously received drug benefits under Medicaid, have their prescription drug costs paid under Part D. Persons with incomes below 150% of poverty have assistance with some portion of their premium and cost-sharing charges. Persons with the lowest incomes have the highest level of benefits.

As of January 2008, approximately 25.4 million Medicare beneficiaries were enrolled in PDP and MA-PD plans. Of these, approximately 9.4 million were receiving low-income subsidy assistance. An additional 6.7 million beneficiaries had prescription drug coverage through a former employer that is receiving a federal subsidy for a portion of such coverage. Approximately 7.5 million beneficiaries had drug coverage through another source. An estimated 4.6 million or 10.4% of Medicare beneficiaries had no drug coverage.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275), which became law July 15, 2008, made a few modifications to the Part D program.

Enrollment in Part D

All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. Beneficiaries enrolled in the "original Medicare" program obtain drug coverage through a PDP.

Beneficiaries enrolled in a managed care plan through a Medicare Advantage (MA) organization generally have to obtain drug coverage through their MA organization. If the MA enrollee wants to enroll in a PDP, he or she must drop their MA enrollment. There is one major exception to this rule. While most MA organizations are required to offer a MA-PD plan, private fee-for-service MA plans are not required to do so.[1] An individual enrolled in a plan not offering drug coverage may purchase coverage through a PDP.

Plan Information

Different PDP and MA-PD plans are available in different parts of the country. Some organizations offer national plans. Information on plan availability and characteristics can be obtained from a number of sources. These include the Medicare toll-free information number (1-800-MEDICARE) and the website [http://www.medicare.gov]. Other organizations may also be able to provide assistance; these include State Health Insurance Assistance Programs (SHIPs) and other local organizations.

Beneficiaries must enroll with the organization offering their selected plan. They can enroll by mail, in person, or on the Web.

Beneficiaries (and persons assisting them) can look for a plan meeting their needs by going to the Medicare drug plan finder on [http://www.Medicare.gov]. An individual using the WEB tool should have a list of all the medications the beneficiary currently takes (together with dosage units). The plan finder will then show the beneficiary the five plans in the area with the lowest total annual cost for the package of drugs the individual takes. It is important to note that *a plan with the lowest premium and/or no deductible may not, in fact, be the lowest cost plan overall*. Further, the lowest cost plan for one member of a couple may not be the lowest cost plan for that person's spouse.

Beneficiaries should review their plan choice annually. Plans can make changes, effective January 1 each year. By October 31, of the previous year, plans are required to provide plan enrollees with a summary of the benefits for the following year and an outline of changes made from the current year. Plans can make a number of changes from one year to the next, including changing drugs included in the plan's formulary and/or changing the required cost-sharing charges for certain drugs. Therefore, enrollees should review materials provided by the plans to make sure that their chosen plans continue to meet their needs.

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[1] See CRS Report RL34151, *Private Fee for Service (PFFS) Plans: How They Differ from Other Medicare Advantage Plans*, by Paulette C. Morgan, Hinda Chaikind, and Holly Stockdale.

Enrollment Periods

Initial Enrollment Period. In general, Medicare beneficiaries need to enroll in a plan during their initial enrollment period in order to avoid the delayed enrollment penalty. Persons on the Medicare rolls when the drug program began had until May 15, 2006 to enroll in a Part D plan for 2006.

Persons eligible for Medicare at a later date have an initial seven-month enrollment period beginning three months before the month of Medicare eligibility. This initial enrollment period is the same as that applicable for Medicare Part B. Coverage for these individuals begins on the first day of the first month following the month of enrollment, but no earlier than the first month they are entitled to Medicare.

Annual Open Enrollment Period. In general, an individual who does not enroll during their initial enrollment period is only able to enroll during the annual open enrollment period, which occurs from November 15-December 31 each year. Coverage begins the following January 1.

Creditable Coverage. Persons who fail to enroll during their initial enrollment period are subject to a penalty if they decide to enroll in Part D at a later date. However, they are not subject to the penalty if they have maintained "creditable" drug coverage through another public or private source. Creditable coverage is defined as drug benefits whose actuarial value equals or exceeds that of standard coverage. Sources of possible creditable coverage are retiree health coverage offered by a former employer or union and military coverage including TRICARE.

A beneficiary who has creditable coverage may wish to enroll in a Part D plan after the conclusion of their initial enrollment period. Care must be taken to assure that any noncoverage period between the two events does not exceed 63 days. Otherwise the beneficiary could be subject to a late enrollment penalty. For example, a retiree who is enrolled in a plan offered by his former employer decides in July 2008 that he wants to drop the employer coverage and enroll in Part D. The individual is not able to enroll in a Part D plan until the annual election period (November 15 to December 31). Coverage will not begin until the following January 1. He will probably want to keep his employer coverage through the end of 2008.

Special Enrollment Periods. In general, individuals can only enroll in Part D during their initial enrollment period or during the annual open enrollment period. However, there are a few limited occasions when an individual may have a special enrollment period including moving to a new geographic area, involuntary loss of creditable coverage; inadequate information provided on creditable coverage status, federal error, termination of a PDP contract, and plan failures. Special enrollment periods also apply for low-income enrollees deemed eligible for a subsidy outside of the initial or annual enrollment periods (See Low-Income discussion, below.)

Late Enrollment Penalty. The Part D delayed enrollment penalty provision is intended to prevent adverse selection. Adverse selection occurs when only those persons who think they need the benefit actually enroll in the program. When this happens, per capita costs are driven up, thereby causing more persons (presumably the healthier, and less costly ones) to drop out of the program. Over time, as more

persons drop out, program costs become prohibitive. The intention of the penalty is to encourage all persons who do not have creditable coverage to enroll. Those who have creditable coverage are maintaining insurance protection and are not deferring coverage until they will actually need it.

The late enrollment penalty is assessed on persons who go for 63 days or longer after the close of their initial Part D enrollment period without creditable coverage and subsequently enroll in Part D. The penalty is based on the number of months the individual does not have creditable coverage. The premium that would otherwise apply is increased for each month without creditable coverage.

The late enrollment penalty is frequently described as being equal to at least 1% of the otherwise applicable premium for each uncovered month. The actual calculation is somewhat more complicated. The law specifies that the penalty is the greater of (1) the amount CMS determines is actuarially sound for each uncovered month or (2) 1% of the *base beneficiary premium* for each uncovered month. The "base beneficiary premium" is a national figure; it may therefore be different than the premium for the plan selected by the beneficiary. For uncovered months occurring during 2006 and 2007 the 1% calculation applies.

The penalty applies for as long as the individual is enrolled in Part D. The dollar amount of the each individual's penalty is expected to increase each year.

As noted above, individuals first eligible for Medicare on or before January 31, 2006, who failed to enroll by May 15, 2006, were not able to enroll until November 15, 2006, with coverage beginning January 1, 2007. If these individuals did not have creditable coverage during the period, they would have seven uncovered months. Their penalty would therefore be 7% of the base beneficiary premium — $1.91 (7% of the base monthly beneficiary premium of $27.35 for 2007). If these same persons waited an additional year, their penalty would be 19% of the base monthly beneficiary premium — $5.31 (19% of the base beneficiary premium of $27.93 for 2008).

Special rules apply for persons who qualify for the low-income subsidy outside of their initial enrollment period or the annual open enrollment period. These individuals can enroll in a Part D plan at any time during the year and not be subject to the late enrollment penalty otherwise applicable to persons who miss the enrollment periods.

Part D Benefits

Qualified Coverage

PDP sponsors and MA-PD plans are required to offer a minimum set of benefits, referred to as "qualified coverage." "Qualified coverage" is defined as either "standard prescription drug coverage" or "alternative prescription drug coverage" with at least actuarially equivalent benefits (i.e., having at least equivalent dollar value). In both cases, access must be provided to negotiated prices for drugs.

Defined Standard Coverage. Standard prescription drug coverage is defined as follows:

- *Deductible* paid by the beneficiary: $275 in 2008.
- 75% of costs paid by the program and 25% of costs paid by the beneficiary up to the *initial coverage limit*: $2,510 in 2008. (In 2008, this represents $833.75 in total out-of pocket costs paid by beneficiary and $2,510 in total spending.)
- 100% of costs paid by the beneficiary for drug spending falling in the *coverage gap up to the catastrophic threshold:* between $2510.01 and $5,726.25 in 2008 (In 2008 this represents $4050 in total out-of pocket costs paid by the beneficiary and $5,726.25 in total spending).
- All costs paid by program over the "catastrophic" threshold or trigger ($5,726.25 in 2008) except for nominal beneficiary cost-sharing. Nominal cost-sharing is defined as the greater of (1) a copayment of $2.25 in 2008 for generic drug or preferred multiple source drug and $5.60 in 2008 for other drugs, or (2) 5% coinsurance.

Each year, the dollar amounts are increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12-month period ending in July of the previous year.

Table 1 shows the standard benefit as well as costs paid by low-income beneficiaries (discussed later in this report).

True Out-Of-Pocket (TROOP) Costs. Beneficiaries must incur a certain level of out-of-pocket costs ($4,050 in 2008) before catastrophic protection begins. Costs are only considered incurred if they are incurred for the deductible, cost-sharing, or benefits not paid because they fall in the coverage gap (sometimes referred to as the *doughnut hole*). Incurred costs do not include amounts for which no benefits are provided because a drug is excluded under a particular plan's formulary. Costs are treated as incurred, and thus treated as true out-of-pocket (*TROOP*) costs only if they are paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, or under a state pharmaceutical assistance program. Any costs for which the individual is reimbursed by insurance or otherwise do not count toward the TROOP amount.

Table 1. Part D Standard Benefits, 2008

(by per capita drug spending category)

Total drug spending (dollar ranges)	All beneficiaries		Subsidy Eligible Individuals[a]			
			Full Subsidy Eligible		Other Subsidy Eligible	
	Paid by Part D	Paid by enrollee	Paid by Part D	Paid by enrollee	Paid by Part D	Paid by enrollee
$0 up to $275 **Deductible**	0%	$275	$275	0	$219	$56
Between Deductible and **Initial Coverage Limit** ($275.01-$2,510)	75%	25%	100% less enrollee cost-sharing	Institutionalized duals: $0 Duals under 100% of poverty: $1.05/$3.10[c] Others: $2.25/$5.60[d]	85%	15%
Between Initial Coverage Limit ($2,5101.01) and **Catastrophic Trigger** ($5,726.25)	0%	100%	100% less enrollee cost-sharing	Institutionalized duals: $0 Duals under 100% of poverty: $1.05/$3.10[c] Others: $2.25/$5.60[d]	85%	15%
Over catastrophic trigger ($5,726.26 and over)	95%[b]	5%[e]	100%	$0	100% less enrollee cost-sharing	$2.25/$5.60[d]

Source: CMS, Notification of Changes in Medicare Part D Payment for Calendar Year 2008 (Part D Payment Notification), Memo to PDP Sponsors, MA organizations and other Interested parties, April 2, 2007.

a. Subsidy eligible persons are low-income individuals entitled to assistance with Part D premiums and cost-sharing. Full-subsidy eligible individuals can enroll in plans for which they pay no premiums; other subsidy eligible individuals can enroll in plans for which a portion of their premiums are subsidized. Both groups have assistance with otherwise applicable cost-sharing charges.

b. Assumes enrollee has met true out-of-pocket (TROOP) threshold of $4,050.

c. $1.05 per prescription for generic or preferred drugs that are multiple source drugs; $3.10 per prescription for other drugs.

d. $2.25 per prescription for generic or preferred drugs that are multiple source drugs; $5.60 per prescription for other drugs.

e. Copayment amounts apply if larger.

Actuarially Equivalent Plans. Plans may offer actuarially equivalent coverage, providing they meet certain requirements. These plans have the same actuarial value as the standard benefit, but a different benefit structure. For example, they may eliminate the deductible, but have cost-sharing requirements higher than the 25% amount under basic standard coverage. They may also used tiered cost-sharing under which generics have the lowest cost-sharing, preferred brands have the next level of cost sharing and nonpreferred brand have higher cost sharing requirements. Some plans may have a specialty tier for very high cost drugs.

CMS recognizes two types of actuarially equivalent plans. Plans labeled "actuarially equivalent standard" offer a different cost-sharing structure. Plans labeled "basic alternative standard" may reduce the deductible, change cost-sharing, and/or change the initial coverage limit. In 2007, 51% of enrollees were in plans offering actuarially equivalent benefits.

Enhanced Coverage. Plans may offer enhanced coverage which exceeds the value of defined standard coverage. This coverage includes both basic coverage and supplemental benefits. Supplemental benefits may include some coverage in the coverage gap (for example coverage of generic drugs) and/or reductions in cost-sharing that increase the actuarial value of the package. In 2007, 35% of enrollees were in plans offering enhanced coverage.

A PDP-sponsor cannot offer an enhanced plan unless it also offers a basic plan in the service area. As noted above, MA organizations offering MA coordinated care plans are required to offer at least one plan in the service area with drug coverage. The drug coverage can be either basic coverage or enhanced coverage with no premium for the supplemental benefits.[2]

Access to Negotiated Prices

All plans are required to provide beneficiaries with access to negotiated prices for covered Part D drugs. This access must be provided even when no Part D benefits are payable because the beneficiary has not met the deductible or the beneficiary is in the coverage gap. Negotiated prices are to take into account negotiated price concessions for covered drugs that are passed through to enrollees at the point of sale. Such price concessions include discounts, direct or indirect subsidies, rebates, and other direct or indirect remunerations.

Special Provisions for Low-Income Populations

A major focus of Part D is the enhanced coverage provided to low-income individuals. Persons with incomes below 150% of poverty (and assets below specified levels) have assistance with some portion of Part D premium and cost-sharing charges. Persons with the lowest incomes have the highest level of assistance.

Eligibility for Low-Income Subsidy (LIS) Assistance

Definition of Eligible Groups. Special premium and cost-sharing subsidies are available for low-income persons. This population is divided into two main groups with the first group divided into subgroups for purposes of determining cost-sharing requirements. The two main groups are defined as follows:

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[2] The only way that there could be no premium for supplemental benefits is if the plan applied a credit of rebate dollars under the plan's Part C bid against the otherwise applicable premium.

"Full Subsidy Eligible Individuals". This group includes all persons who (1) are enrolled in a PDP plan or MA-PD plan; (2) have incomes below 135% of the federal poverty level ($14,040 for an individual and $18,900 for a couple in 2008); and (3) have resources in 2008 below $6,290 for an individual and $9,440 for a couple (increased each year by the percentage increase in the consumer price index, or CPI). The 2008 resource limits are generally publicized as $7,790 and $12,440 because $1,500 per person is excluded for burial expenses.

The following groups of persons are also defined as full subsidy eligible individuals:

- *Dual Eligibles*. These are persons entitled to the full range of benefits under their state's Medicaid program. Prior to January 1, 2006, these persons received their drug benefits under Medicaid. Effective January 1, 2006, their drug benefits are provided through Part D. All full benefit dual eligible individuals are deemed to be in the full subsidy eligible group, regardless of whether they meet the other eligibility requirements.

- *Recipients of Supplemental Security Income (SSI) benefits*; or

- *Enrollees in a Medicare Savings Program (MSP)*. MMA permitted the Secretary to extend full subsidy eligible coverage to enrollees in MSP. (Implementing regulations extended coverage to this group). There are three Medicare Savings programs that provide Medicaid assistance for Medicare premiums and cost-sharing charges. The three groups are (1) qualified Medicare beneficiaries (QMBs),[3] (2) specified low-income Medicare beneficiaries (SLMBs),[4] and (3) qualifying individuals (QIs).[5]

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[3] QMBs are aged or disabled persons with incomes at or below the federal poverty level. In 2008, the monthly level is $887 for an individual and $1,187 for a couple (these levels include a monthly $20 disregard for unearned income). Assets must be below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges and the Medicare Part B premium paid by the federal-state Medicaid program. Medicaid protection is limited to payment of Medicare cost-sharing charges (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services, such as long term care) unless the individual is otherwise entitled to Medicaid.

[4] SLMBs meet the QMB criteria, except that their income is between 100% and 120% of the federal poverty level. In 2008, the monthly income limits are $1,060 for an individual and $1,420 for a couple. Medicaid protection is limited to payment of the Medicare Part B premium (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid.

[5] These are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. Further, they are not otherwise eligible for Medicaid. In 2008, the monthly income limit for QI for an individual is $1,190 and for a couple $1,595. Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium. Note that in 2010, the resource limits under the MSP programs are raised to the level applicable for full subsidy eligible Part D enrollees.

"Other Subsidy Eligible Individuals". This group includes all other persons who (1) are enrolled in a PDP plan or MA-PD plan, (2) have incomes below 150% of poverty ($15,600 for an individual and $21,000 for a couple in 2008), and (3) have resources in 2008 below $10,490 for an individual and $20,970 for a couple (increased in future years by the percentage increase in the CPI). The publicized resource limits of $11,990 and $23,970 include a $1,500 per person burial allowance.

Definition of Income and Assets. The definitions of income and assets generally follows that used for determining eligibility under the QMB, SLMB, and QI-1 programs (which in turn link back to the definitions used for purposes of the SSI program). There are, however, a few items that should be noted:

- *Family Size*. Currently, the federal poverty level (FPL) used for income determinations is that applicable for an individual or for a couple. MMA specified that the FPL is to be that for the family of the size involved. Therefore, the regulations define the family size to include, in addition to the applicant and spouse, additional persons related to the applicant who live in the same residence and depend on the applicant or spouse for at least one-half of their financial support. The income of these additional persons would not, however, be used in the determination of eligibility.

- *Resources*. MMA provides for the development of a simplified application in which applicants attest to their level of resources and submit minimal documentation. Only liquid resources (or those that could be converted to cash within 20 days) and real estate that is not the applicant's primary residence are considered. Liquid resources include such things as checking and savings accounts, stocks, and bonds. Vehicles are excluded because they are not considered liquid assets.

- *More Generous State Standards*. The law (Section 1902(r)(2) of the Social Security Act) allows states to use more generous income and assets rules for determining eligibility for the QMB, SLMB, and QI-1 programs. A few states have elected this option. As noted above, MMA permitted the Secretary to include all persons meeting QMB, SLMB, and QI-1 criteria in the full subsidy eligible group; the Secretary elected to do so. However, only persons on QMB, SLMB, or QI-1 rolls are actually included. States are not permitted to use the less restrictive methodologies for other subsidy eligibility determinations; the standards will be the same nationwide for these persons.

- *Exemptions from Income and Resources*. Effective January 1, 2010, support and maintenance furnished in kind will be excluded from the definition of income. Further, any part of the value of any life insurance policy will be excluded from the definition of resources.

LIS Benefits

Subsidies are provided for both premiums and cost-sharing charges.

Premium Subsidies. Premium subsidies are available for both full subsidy eligible and other subsidy eligible persons. However, the amount of assistance is less for the second group.

Full Subsidy Eligible Individuals. All full subsidy-eligible individuals receive a premium subsidy equal to 100% of the low-income benchmark premium amount (see following discussion), but in no case higher than the actual premium amount for basic coverage under the plan selected by the enrollee.

In addition, the premium subsidy amount can not be less than the premium for the lowest-cost PDP plan in the region. Thus, all full subsidy eligible individuals are entitled to a full premium subsidy for at least one plan in their region. However, if a beneficiary selects a plan with a premium higher than the benchmark, the beneficiary is liable for the additional costs.

Full subsidy eligible individuals, but not other subsidy eligible individuals, also have a premium subsidy for any Part D late enrollment penalty equal to 80% for the first 60 months of delayed enrollment and 100% thereafter.

Other Subsidy Eligible Individuals. All other subsidy eligible individuals have a sliding scale premium subsidy ranging from 100% of the premium subsidy amount at 135% of poverty to 0% of such value at 150% of poverty. Specifically, the subsidy is 75% for persons with incomes above 135% but at or below 140% of poverty, 50% for persons with incomes above 140% but at or below 145% of poverty; and 25% for persons with incomes above 145% but below 150% of poverty.

Calculation of Low-Income Benchmark Premium. The low-income benchmark premium for a region is the weighted average of the monthly beneficiary premiums for basic prescription drug coverage. The low-income benchmark is defined as the weighted average premium, with the weight based on plan enrollment. For 2006, the program's first year, all PDPs were assigned an equal weight. (MAs were enrollment weighted if they had 2005 enrollment.)

Beginning in 2007, the bid amounts were to be weighted by plan enrollment in the previous year. However, since many beneficiaries selected low-cost plans in 2006, using a weighted average would have the effect of reducing the regional low-income benchmark premium amounts. Instead, CMS decided to transition to the weighting methodology using the Secretary's demonstration authority ("Medicare Demonstration to Transition Enrollment of Low-Income Subsidy Beneficiaries"). For 2007, it used the same methodology used for 2006. Beginning for 2008, it is implementing a transition from the 2006 methodology and the weighted average method based on actual plan enrollments. In 2008, 50% of the regional benchmark is based on the 2006 averaging methodology and 50% on the enrollment-weighted average. For determining the enrollment-weighted average, Part D enrollees in PDPs and MA-PDs in June 2007 are used. **Table 2** shows the applicable 2008 amount by PDP region.

Table 2. Low-Income Benchmark, by Region, 2008

Region	State(s)	Monthly Subsidy		Region	State(s)	Monthly Subsidy
1	NH, ME	$30.64		18	MO	$26.71
2	CT, MA, RI, VT	29.17		19	AR	27.69
3	NY	24.18		20	MS	31.35
4	NJ	31.23		21	LA	24.62
5	DE, DC, MD	30.78		22	TX	25.01
6	PA, WV	26.59		23	OK	28.04
7	VA	31.03		24	KS	30.62
8	NC	33.43		25	IA, MN, MT, ND, NE, SD, WY	30.61
9	SC	31.12		26	NM	19.28
10	GA	30.04		27	CO	24.59
11	FL	19.16		28	AZ	15.92
12	AL, TN	28.29		29	NV	16.64
13	MI	30.49		30	OR, WA	30.19
14	OH	26.82		31	ID, UT	33.53
15	IN, KY	33.50		32	CA	19.80
16	WI	31.03		33	HI	24.32
17	IL	30.26		34	AK	36.42

Source: CMS, at [http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/RSD/list.asp#TopOfPage].

Cost-Sharing Subsidies. Cost-sharing subsides are linked to "standard prescription drug coverage." Full subsidy eligibles have no deductible, no coverage gap (i.e., no "doughnut hole"), and no cost-sharing over the catastrophic threshold. Full benefit dual eligibles who are residents of a medical institution or nursing facility have no cost-sharing. Other full benefit dual eligible individuals with incomes up to 100% of poverty have cost-sharing, for all costs up to the out-of-pocket threshold, of $1.05 in 2008 for a generic drug prescription or preferred multiple source drug prescription and $3.10 in 2008 for any other drug prescription. All other full subsidy eligible individuals have cost-sharing, for all costs up to the out-of-pocket threshold, of $2.25 in 2008 for a generic drug or preferred multiple source drug and $5.60 in 2008 for any other drug. (See **Table 1**.)

Other subsidy eligible individuals have a $56 deductible in 2008, 15% coinsurance for all costs up to the catastrophic trigger level, and cost-sharing for costs above this level of $2.25 in 2008 for a generic drug prescription or preferred

multiple source drug prescription and $5.60 in 2008 for any other drug prescription. (See **Table 1**.)

Each year, the cost-sharing amounts for full benefit dual eligibles below 100% of poverty are increased by the increase in the CPI. The cost-sharing amounts for all other persons, and the deductible amount for other subsidy eligible individuals, are increased by the annual percentage increase in per capita beneficiary expenditures for Part D covered drugs.

Enrollment

Generally there is a two-step process for low-income persons to gain Part D coverage. First, a determination must be made that they qualify for the assistance; and, second, they must enroll, or be enrolled, in a specific Part D plan. Special procedures were established to make the process easier. The procedures are different for different categories of low-income enrollees.

Dual Eligibles. There were more than 6 million dual eligibles who needed to be enrolled in a Part D plan, effective January 1, 2006. CMS established an auto-enrollment process which was intended to assure there was no gap in coverage, though the program did encounter some problems in the early stages.

The auto-enrollment process was random among plans with premiums at or below the low-income benchmark premium. Persons becoming dually eligible after January 2006 are also auto-enrolled into a Part D plan.

There are a number of differences among available plans. Key differences are drugs included in plan formularies and pharmacies participating in the plan as network pharmacies. Some dual eligibles may find that they are auto-enrolled in a plan which may not best meet their needs. For this reason, they are able to change enrollment at any time with the new coverage effective the following month. It should be noted that if an enrollee selects a plan with a premium above the low-income benchmark, he or she is required to pay the difference.

Enrollees in Medicare Savings Programs. CMS established a process, labeled "facilitated enrollment" for enrollees in Medicare Savings programs (MSPs), SSI enrollees, and persons who applied for and were approved for low-income subsidy assistance. The basic features applicable to auto-enrollment for dual eligibles (i.e., random assignment to plans with premiums below the low-income benchmark and assignment of MA enrollees to the lowest-cost MA-PD plan offered by the MA organization) were extended to facilitate enrollment.

Beneficiaries eligible for facilitated enrollment in 2006 were sent notices informing them of the plans they would be enrolled in if they took no action. If the beneficiary failed to select another plan (and did not decline Part D enrollment), he or she was considered to have enrolled in the assigned plan, effective May 1, 2006. Facilitated enrollment also applies for persons becoming eligible for MSP after that date. As is the case for a dual eligible, an MSP enrollee can change plan enrollment throughout the year.

Other Low-Income Persons. MMA extended low-income subsidies to all persons with incomes below 150% of poverty and assets below specified levels. Persons not identified as dual eligibles, MSP enrollees, or SSI recipients may qualify, but they need to submit an application. The Social Security Administration (SSA) generally makes eligibility determinations for those who fill out the applications, though an individual may request the state Medicaid agency to make the determination.

CMS facilitates enrollment in Part D plans for persons identified as qualifying for extra help. However, unless they are dual eligibles or MSP enrollees, they are only able to switch plans once during the year, with the new coverage effective the following month.

2008 Enrollment. There are several circumstances under which a low-income subsidy-eligible person experienced a change from 2007 to 2008. These include cases in which an individual (1) was enrolled in a plan in 2007 whose 2008 premium would no longer fall below the low-income benchmark premium, (2) was enrolled in a plan that terminated its participation in Part D, (3) lost automatic eligibility for the low-income subsidy in 2008, or (4) fell into a different subsidy category.

Individuals Enrolled in Plans in 2007 that no Longer Have Premiums Below the Benchmark or in Plans that Terminate. CMS established a process for reassigning these beneficiaries to a different Part D plan. Beneficiaries that were reassigned had to meet all of the following criteria:

- They were deemed eligible for a subsidy in 2007 because they were dual eligibles, participants in MSP, SSI recipients, or because they applied and were found eligible for the full subsidy.
- They would continue to be eligible for a subsidy in 2008.
- They were originally auto-enrolled or had their enrollment facilitated into a PDP.
- They did not elect to enroll in a different plan.
- Their 2007 plan had a 2008 premium that was above the "de minimus amount" (which is the benchmark plus $1) or terminated at the end of 2007.

Beneficiaries meeting all of these criteria were reassigned to a different PDP in the region as follows. The beneficiaries were assigned to another plan in the same region offered by the same PDP sponsor, if the sponsor had a plan with a premium at or below the benchmark (or, if there was none available, a plan below the de minimus amount). If no such plan existed, CMS randomly assigned beneficiaries among PDP sponsors with at least one plan with a premium at or below the benchmark. CMS notified beneficiaries in early November 2007 of their plan assignment; they were reassigned to a new plan effective January 1, 2008. However, beneficiaries could voluntarily elect to stay in their existing plan (if it was still offered) or select a different plan from the one assigned by CMS.

Beneficiaries who changed plans after they were either auto-assigned to a plan or had their enrollment facilitated into a plan did not have their selection changed by CMS. However, they were informed that their plan's premium was rising above the regional low-income subsidy amount by more than the de minimus $1 in 2008 and would therefore be liable for any excess if they stayed with their current plan. The beneficiary was free to change his or her selection.

On October 29, 2007, CMS announced that it was sending reassignment notices to 1.6 million persons who would be reassigned to a new plan outside of their current organization and an additional 965,000 persons who were to be reassigned to a new plan within their current organization. It also announced that it was sending "chooser notices" to the 442,000 persons who qualified for a full premium subsidy but the 2007 plan they had selected would have a premium in 2008 above the de minimus amount.

Individuals Losing Automatic Eligibility for Low-Income Subsidy. Persons automatically qualifying for a low-income subsidy are dual eligibles, persons enrolled in MSP, and SSI recipients. In September 2007, CMS sent letters to those beneficiaries losing their automatic eligibility for a low-income subsidy in 2008 because they no longer fell into one of these categories. At the same time, these beneficiaries were told they still might qualify for assistance and were encouraged to file a low-income subsidy application with SSA. The application and a postage-paid envelope were enclosed with each notice.

Individuals Falling Into a Different Subsidy Category. Beneficiaries who would experience a change in their low-income subsidy level in 2008 received a notice in October 2007 informing them of the change. These beneficiaries are subject to different cost-sharing requirements.

Interaction with State Pharmacy Assistance Programs

A number of states have had state pharmaceutical assistance programs (SPAPs) in place for a number of years. These programs were set up to offer prescription drug benefits to low-income individuals who did not have Medicaid drug coverage. Many, but not all, persons enrolled in SPAPs are eligible for low-income subsidies under Part D. SPAP payments made on their behalf to cover Part D cost-sharing charges count toward the individual's true out-of-pocket (TROOP) costs trigger.

MMA defines an SPAP as one that provides assistance to persons in all Part D plans and does not discriminate based on the Part D plan in which the individual is enrolled. CMS interpreted the Part D language to mean that if an SPAP offers Part D premium assistance or supplemental Part D cost-sharing assistance, it must offer equal assistance for all PDP and MA-PD plans available in the region, and may not steer beneficiaries to one plan or another through benefit design or otherwise. Violation of this nondiscrimination rule would violate the SPAP's status with respect to counting TROOP. The inability to steer beneficiaries to a selected plan or plans effectively meant that an SPAP could not auto-enroll its participants in preferred Part D plans. This proved to be a concern for some states who argued they should be able to enroll their beneficiaries in preferred plans if they gave individuals the option to switch to other plans if they wanted to.

CMS established policies intended to balance the need to adhere to the nondiscrimination requirement with state concerns. It generally required SPAPs to provide wrap-around benefits (namely fill in the gaps) for their Part D beneficiaries regardless of the plan the beneficiary chose to enroll in and permitted SPAPS (when acting as authorized representatives) to enroll their beneficiaries in Part D plans using only beneficiary-specific criteria to limit the selection of part D plans. In its 2008 call letter to plans, CMS refined the policy to explicitly permit states to adopt reasonable coordinating criteria. SPAPs with authorized representative status are allowed to facilitate enrollment of their beneficiaries into plans that agree to the state-specific coordination criteria (such as offering similar formularies and pharmacy network structures). Such criteria must be of the kind that any Part D plan could meet if it chose. SPAPs must continue to permit beneficiaries who wish to enroll in a plan not meeting the coordinating criteria to do so; they must provide the same wrap-around benefits or assistance.

Part D Plans

PDP Regions

MMA required the Secretary to designate PDP regions. The service area for a PDP plan must include the entire PDP region. A plan can be offered in more than one PDP region, including all PDP regions.

The Secretary designated 34 PDP regions. No region is smaller than a state. Twenty-five states are individual regions. Twelve states are part of two state regions. There is one region with two states and the District of Columbia, one region with four states, and one region with seven states. (See **Table 2** for states in each region.)

Approval of PDP Plans

Each year, CMS issues a call letter to contractors planning to offer PDP and/or MA plans in the coming year. The 2008 call letter issued in April 2007, combined contracting guidance for both programs. Potential PDP and MA sponsors are required to submit bids by the first Monday in June of the previous year. Each potential PDP sponsor is required to submit a bid and supplemental information for each Part D plan it intends to offer. The following information is to be included with the bid: (1) the coverage to be provided; (2) actuarial value of qualified prescription drug coverage in the region for a beneficiary with a national average risk profile; (3) information on the bid including the basis for the actuarial value, the portion of the bid attributable to basic coverage and, if applicable, the portion attributable to enhanced coverage, and assumptions regarding the reinsurance subsidy (see discussion on financing, below); and (4) service area.

CMS reviews the information to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. Private fee-for-service plans under Medicare Part C are exempt from the negotiation requirements.

MMA specified that the negotiating authority is similar to the authority the Director of the Office of Personnel Management has with respect to Federal Employees Health Benefits (FEHB) plans. However, the law specifically states that the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors. Further, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs. This is know as the "non-interference provision."

CMS can only approve a plan if certain requirements are met. The plan must comply with Part D requirements, including those relating to beneficiary protections. CMS must determine that the plan and the sponsor meet requirements relating to actuarial determinations. Further, the Secretary may not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to discourage enrollment by certain beneficiaries.

For both 2007 and 2008, CMS negotiated with plan sponsors to ensure that each bid submitted represented a meaningful variation based on plan characteristics that would provide beneficiaries with substantially different options. CMS has stated that it would not expect that more than two bids from a sponsoring organization would provide meaningful variation unless one of the bids is an enhanced alternative plan with coverage in the gap.

Contracts

The law and regulations establish requirements for PDP plan sponsors. In general, a PDP sponsor must be licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each state in which it is offering a drug plan. (Alternatively, it could meet solvency standards established by CMS for entities not licensed by the state.) The entity must assume its financial risk on a prospective basis for covered benefits; it may obtain insurance (i.e., reinsure) or make other arrangements for the costs of coverage.

PDP sponsors enter into contracts with CMS. The contract may cover more than one Part D plan. Under terms of the contract, the sponsor agrees to comply with Part D requirements and have satisfactory administrative and management arrangements.

CMS cannot enter a contract with an organization unless it meets minimum enrollment requirements of 5,000 individuals (or 1,500 individuals if the organization primarily serves individuals residing outside of urbanized areas). CMS may waive the minimum enrollment requirement during the first contract year for a sponsor in a region.

Each contract is for a period of 12 months. An entity is determined qualified to renew its contract annually only if CMS informs the entity that it is qualified to renew the contract and the plan sponsor has not provided CMS of a notice of its intent not to renew. However, renewal of a contract is contingent on reaching agreement on the bid. If the sponsor and CMS cannot reach agreement, no renewal takes place.

Plan Monitoring

CMS monitors plan operations with particular emphasis on the following five performance measures: telephone customer service wait times; frequency and types of complaints; timeliness and resolution of appeals; completeness of enrollment information available to pharmacists; and the percent of drug pricing changes available on the drug plan finder on the WEB and the percent of drugs on the finder with price increases.

Drug Payments

Part D plan sponsors (or the pharmaceutical benefit managers (PBMs) they have contracted with) negotiate prices with drug manufacturers, wholesalers and pharmacies. The negotiated price (i.e., the price that is available to the beneficiary) is net of some or all of rebates, discounts and other price concessions. The plan's negotiated price may reflect the same prices that a health plan or PBM would get for its commercially insured members or it may be different.

Part D plans are expected to negotiate on behalf of enrollees for price discounts. These discounts may be passed on to beneficiaries and the program in many ways including lower copayment and coinsurance, lower prices (compared with retail prices), and lower premiums. A portion of the manufacturers price concessions may be retained by the plan.

Plan sponsors negotiate with pharmacies in order to include a sufficient number and geographic distribution of pharmacies in their networks. The plan reimburses the pharmacy for the cost of the drug, plus a dispensing fee. Pharmacies set their own rates for dispensing drugs but may give the plan a discount on their usual rate.

A plan's negotiated prices may be found on the www.medicare.gov website. Beneficiaries can also compare negotiated prices for different plans in their area. By law, the net prices charged to Part D plans are not made public. The amount of price concessions is reported to CMS.

The 2008 Medicare trustees report estimated the average rebate at 9% for 2008; it was expected to remain at that level through 2017. As noted above, some but not necessarily all, of these savings may be passed on to beneficiaries.

Plan Characteristics/Beneficiary Protections

The law and regulations establish requirements that plans must meet.

Marketing/Beneficiary Communications

Plan sponsors are required to assure timely and accurate information in their marketing materials. Such materials must be approved by CMS. In its 2008 call letter to plans, CMS emphasized that organizations are responsible for the actions of

sales agents/brokers whether they are employed or contracted. It stated that organizations must assure that these individuals are properly trained in both Medicare and the details of the products being offered. Plan sponsors must provide strong oversight of marketing activities.

Employees of an organization or independent agents or brokers acting on behalf of the organization may not solicit Medicare beneficiaries door-to-door. They must first ask permission before providing assistance in a beneficiary's home, prior to conducting any sales representations or accepting an enrollment form in person.

Plan sponsors are required to provide enrollees with an evidence of coverage (EOC) document upon enrollment and annually thereafter. The EOC gives the details about how the plan works, covered benefits and related cost-sharing responsibilities. Plans are also required to provide current enrollees with an annual notice of change (ANOC) document, showing changes for the forthcoming year, prior to the annual open enrollment period. The ANOC does not provide a list of drugs added or deleted from the formulary or drugs whose tier has changed. It does however note if such changes have been made.

For the 2008 plan year, plan sponsors were encouraged to use a combined model ANOC/EOC document to be forwarded to beneficiaries by October 31, 2007; in addition they were required to mail information on plan formularies. Alternatively, plans could use a separate ANOC and statement of benefits, with the EOC to follow by January 31, 2008.

In its draft 2008 call letter, CMS had considered allowing plan comparisons of MA and PDPs in a specific service area. However, CMS stated that based on negative response to the proposal, it was persuaded that it was not practical or meaningful to develop a comparison that was not beneficiary specific.

As noted earlier, beneficiaries can obtain targeted information about plans by using the Medicare prescription drug plan finder tool on the www.medicare.gov website. Information for 2008, was posted October 11, 2007.

Covered Drugs

In order for a drug to be paid under Part D, it must be a drug that can be included under Part D. Further, it must be included in the formulary of the individual's Part D plan.

Covered Drugs. The law defines covered Part D drugs as (1) outpatient prescription drugs approved by the Food and Drug Administration (FDA), and used for a medically accepted indication; (2) biological products which may only be dispensed upon a prescription and which are licensed under the Public Health Service (PHS) Act and produced at a licensed establishment; (3) insulin (including medical supplies associated with the injection of insulin); and (4) vaccines licensed under the PHS Act. Also included are drugs treated as being included in a plan's formulary as a result of a coverage determination or appeal.

Excluded Drugs. The law specifically excludes drugs which may be excluded from coverage under Medicaid, except for drugs used for smoking cessation. This exclusion applies to (1) benzodiazepines;[6] (2) barbiturates;[7] (3) drugs used for anorexia, weight loss, or weight gain; (4) fertility drugs; (5) drugs used for cosmetic purposes or hair growth; (6) drugs for symptomatic relief for coughs and colds; (7) prescription vitamins and minerals; and (8) covered drugs when the manufacturer requires, as a condition of sale, that associated tests be purchased exclusively from the manufacturer. In addition, drugs which are used for the treatment of sexual or erectile dysfunction are excluded, unless they are used to treat another condition for which the drug has been approved by the FDA (off label uses for these drugs are not covered).

It should be noted that a Part D sponsor may elect to include one or more of these drugs in an enhanced Part D plan. However, no federal subsidy is available for the associated costs.

Part B Versus Part D. Part D will not pay for drugs which are covered under Part B (even if the individual is not actually enrolled in Part B). Some drugs and vaccines can potentially be covered under both Part B or Part D. In this case a determination must be made as to whether or not the drug can be covered under Part B in the particular case. Part B covered drugs include drugs which are not usually self-administered and provided incident to a physicians's professional services; immunosuppressive drugs for persons who have had a Medicare-covered transplant; erythropoietin for persons with end stage renal disease; oral anti-cancer drugs; drugs requiring administration via a nebulizer or infusion pump in the home; and certain vaccines (influenza, pneumococcal, and hepatitis B for intermediate or high risk persons).

Vaccine Administration. Beginning in 2008, Part D plans (not Part B) are required to cover the costs for the administration of Part D covered vaccines. Physicians will need to bill the patients for these services; the patient will then need to bill the Part D plan.

Formularies

Part D formularies are required to meet a number of specific requirements.

Pharmacy and Therapeutic (P&T) Committee. A P&T committee must develop and review the formulary. A majority of the members must be practicing physicians, practicing pharmacists or both. Further, they must come from clinical specialties that adequately represent the needs of beneficiaries.

The committee, when developing and reviewing the formulary, is to base clinical decisions on the strength of scientific evidence and standards of practice. It

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[6] Effective January 1, 2013, plans will be required to include benzodiazepines in their formularies.

[7] Effective January 1, 2013, plans will be required to include barbiturates in their formularies for the indications of epilepsy, cancer, or chronic mental health disorder.

should also take into account whether including a particular drug in the formulary (or in a particular tier in the formulary) has therapeutic value in terms of safety and efficacy.

Minimum Requirements. The formulary must include drug categories and classes that cover all disease states. MMA required CMS to request the United States Pharmacopeia (USP) to develop a list of categories and classes which may be used by plans and to periodically revise such classification as appropriate. Part D plans that use a classification system that is consistent with the USP classification system are deemed to satisfy a safe harbor and will be approved by CMS. CMS will review systems of plans proposing to adopt an alternative classification to determine if it is similar to the USP or other commonly used system.

A plan's formulary must include at least two drugs in each category or class (unless only one drug is available in the category or class, or two drugs are available but one drug is clinically superior). The two drug requirement must be met through the provision of two chemically distinct drugs. Plans cannot meet the requirement by including only two dosage forms or strengths of the same drug or a brand name and its generic equivalent. However, CMS does expect plans to include multiple strengths and dosage forms where available.

Six Classes of Clinical Concern. CMS has required Part D to cover all, or substantially all of the drugs in the following six drug categories: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. CMS instituted this policy to mitigate the risks and complications associated with an interruption of therapy for vulnerable populations. For 2008, the requirement applies to drugs available on April 16, 2007. New drugs or newly approved drugs within these six classes that come into the market at a later date will be subject to expedited P&T committee review.

Plan sponsors cannot implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for beneficiaries currently taking a drug. For beneficiaries beginning treatment in these categories, such management techniques may be used for categories other than HIV/AIDS drugs.

Beginning with plan year 2010, the Secretary will be required to identify categories and classes of drugs (which may be different from the six classes required by CMS) for which (1) restricted access to the category or class will have major or life-threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class, and (2) there is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer. Prescription drug plan (PDP) sponsors will be required to include all covered Part D drugs in the categories and classes identified by the Secretary. However, the Secretary may establish a formal exceptions process that ensures that any exception is based on scientific evidence and medical standards of practice (which for antiretroviral medications must be consistent with HHS Guidelines for the Use of Antiretroviral

Agents in HIV-1-Infected Adults and Adolescents), and includes a public notice and comment period.

CMS Review. CMS reviews and approves drug lists that are consistent with best practice formularies currently in widespread use. It reviews formularies for at least one drug in each of the USP Formulary Key Drug Types. It reviews tier placement to provide assurance that the formulary does not substantially discourage enrollment of certain beneficiaries. It analyzes formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines which are indicative of general best practice. It also analyzes the availability and tier position of the most commonly prescribed drug classes for the general Medicare population and the dually eligible population. CMS also looks to existing best practices to check plans' use of utilization management tools such as prior authorization, quantity limits and step therapy (where a lower cost drug is first tried before a higher cost drug may be used).

For the 2008 contract year, CMS stated that it was expanding its review of drugs commonly used by the dual eligible population to 200 and incorporating the top 100 drugs used in the Medicare drug discount card program (the temporary program for the low-income persons in place in 2004-2005). It was also expanding the number of treatment guidelines to ensure best practice drugs are included in the formulary. Finally, it would use the presence of USP Formulary Key Drug Types as an outlier test to ensure these drugs are strongly represented on all Part D formularies.

Specialty Tier. A Part D plan is allowed to exempt a formulary tier in which it places very high cost and unique items from tiered cost-sharing exceptions. In order to ensure that the plan does not substantially discourage enrollment by specific patient populations, CMS will only approve specialty tiers under the following conditions:

- There is only one specialty tier exempt from cost-sharing exceptions.
- Cost-sharing is limited to 25% in the initial coverage range (or actuarially equivalent for plans with decreased or no deductible basic alternative design).
- Only plans with negotiated prices exceeding a threshold may be placed in the tier. The level is $500 a month in 2007 and $600 a month in 2008.

Formulary Changes During Plan Year. MMA provided that if plans removed drugs from their formularies during the year (or changed their preferred or tiered status), they were required to provide notice, on a timely basis, to CMS, affected enrollees, physicians, pharmacies and pharmacists. Observers expressed concerns about the implications of formulary changes on plan enrollees. In response, CMS emphasized that best practices call for limited changes during the plan year and outlined the following circumstances under which such changes can be made:

- Plans can expand formularies by adding drugs, lowering the tier of a drug (thereby reducing copayments or coinsurance), or deleting utilization management requirements.

- Plans can not change therapeutic categories and classes during a year except to account for new therapeutic uses and newly approved Part D drugs.

- Plans can make formulary maintenace changes after March 1, such as replacing a brand name drug with a new generic drug or modifying formularies as a result of new information on safety or effectiveness. These changes require approval and 60 days notice to appropriate parties.

- Plans can only remove drugs from a formulary, move covered drugs to a less preferred tier status, or add utilization management requirements in accordance with approved procedures and after 60 days notice to appropriate parties. *Plans can make such changes only if enrollees currently taking the affected drugs are exempt from the formulary change for the remainder of the plan year.*

Plans are not required to obtain CMS approval or give 60 days notice when removing formulary drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

Transition Policies. CMS has established transition standards intended to assure that new plan enrollees do not abruptly lose coverage for their drugs. Specifically, plans are required to provide a temporary supply fill anytime within the first 90 days of a beneficiary's enrollment in a plan. The supply must be for 30 days (unless the prescription is written for less than 30 days) for any nonformulary drug. The requirement also applies to drugs that are on a plan's formulary, but that require prior authorization or step therapy. In long-term care facilities, the transition policy provides for a 31-day fill, with multiple fills as necessary, during the first 90 days of a beneficiary's enrollment in a plan. After the 90-day period, the plan must provide a 31-day emergency supply while an exception is being processed. (CMS has specified 31 days because many long-term care pharmacies dispense medications in 31-day increments.) For contract year 2008, sponsors are required to ensure that the transition process information is prominently posted on their website.

CMS has noted that the purpose of the process is not just to provide a temporary fill of non-formulary drugs but rather to provide enrollees with sufficient time to work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request an exception based on grounds of medical necessity.

Formulary Change Notice in Advance of Upcoming Year. As noted earlier, enrollees must receive an annual notice of change (ANOC) by October 31 prior to the next contract year. The upcoming year's formulary is viewed as a new formulary; therefore CMS does not require plans to identify specific drug changes

impacting enrollees or require 60 days notice of change. However, enrollees have at least 60 days to review the new formulary and identify any changes.

CMS has outlined two options for providing a transition for enrollees whose drugs are no longer on the formulary. They may provide a transition process for current enrollees consistent with the transition process for new enrollees beginning January 1 of the new contract year. Alternatively, they can effectuate a transition for current enrollees prior to January 1. However, if plans have not successfully transitioned the affected enrollees to a therapeutically equivalent formulary alternative or processed an exceptions request by January 1, they are expected to provide a transition supply beginning January 1 until such time as they have effected a meaningful transition.

Pharmacy Access

PDP sponsors are required to establish a pharmacy network sufficient to ensure access to covered Part D drugs for all enrollees. They must demonstrate that they provide (1) convenient access to retail pharmacies for all enrollees, (2) adequate access to home infusion pharmacies for all enrollees, (3) convenient access to long-term care (LTC) pharmacies for residents of LTC facilities, and (4) access to Indian Health Service, Tribes, or Urban Indian Programs (I/T/U) pharmacies operating in the sponsor's service area.

CMS can waive the standards in the case of (1) MA-PD plans that operate their own pharmacies, provided they can demonstrate convenient access, and (2) private-fee-for-service plans offering Part D coverage for drugs purchased from all pharmacies, provided they do not charge additional cost-sharing for drugs obtained from non-network pharmacies.

Retail Pharmacy Access. MMA defined convenient access to retail pharmacies as being no less favorable than those standards specified for the Department of Defense TRICARE regional pharmacy program as of March 13, 2003. The applicable Part D standards are as follows:

- In urban areas, at least 90% of Medicare beneficiaries in the plan's service area, on average, live within 2 miles of a retail pharmacy participating in the plan's network.
- In suburban areas, at least 90% of Medicare beneficiaries in the plan's service area, on average, live within 5 miles of a retail pharmacy participating in the plan's network.
- In rural areas, at least 70% of Medicare beneficiaries in the plan's service area, on average, live within 15 miles of a retail pharmacy participating in the plan's network.

The inclusion of mail order pharmacies in Part D plan networks is optional. However, such plans do not count toward meeting the retail pharmacy access requirements. Plans that include mail order pharmacies in their networks must allow enrollees to receive benefits, such as extended (e.g., 90-day) supply of covered drugs

through a network retail pharmacy. However, beneficiaries making this choice could be subject to higher cost sharing charges.

Part D sponsors may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies ("specialty pharmacies"), except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of drugs that require extraordinary special handling, provider coordination, or patient education when such requirements cannot be met by a network pharmacy.

Long-Term Care (LTC) Pharmacy Access. Part D sponsors must offer standard LTC pharmacy network contracts to all LTC pharmacies operating in their service area that request such contracts. The pharmacy must be able to meet performance and service criteria specified by CMS as well as any standard terms and conditions established by the Part D sponsor for its network LTC pharmacies. Part D sponsors may not rely on out-of-network pharmacies to meet the LTC convenient access standards.

"Any Willing Pharmacy". Part D sponsors are required to permit any pharmacy willing to accept the sponsor's standard contracting terms and conditions to participate in the plan's network. CMS notes that the sponsors standard terms and conditions may vary to accommodate geographic areas and types of pharmacies. However, all similarly situated pharmacies are to be offered the same standard terms and conditions.

A Part D pharmacy may not require a network pharmacy to accept insurance risk as a condition of participation in its pharmacy network.

Payments to Pharmacies

MIPPA included provisions directed at prompt payments and related issues. For plan years beginning on or after January 1, 2010, the negotiated contracts between pharmacies and PDP sponsors or MA-PD plans will be required to provide that payment will be issued, mailed, or otherwise transmitted with respect to all "clean claims" submitted by pharmacies within the "applicable number of calendar days" after the date on which the claim is received. This requirement will not apply to pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility. "Clean claims" are defined as those claims that have no defect or impropriety such as the lack of any required substantiating documentation, or any circumstances requiring special treatment that prevents timely payment from being made. Claims submitted electronically will be considered to have been received on the date on which the claim is transferred. Claims not submitted electronically will be considered to have been received on the fifth day after the postmark date of the claim or the date specified in the time stamp of the transmission. The term "applicable number of calendar days" will be defined as 14 days for claims submitted electronically and 30 days for claims submitted otherwise. If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days after a clean claim is received, the PDP sponsor or MA-PD plan will be required to pay interest to the pharmacy that submitted the claim.

MIPPA also provided that for plan years beginning on or after January 1, 2010, contracts between PDP sponsors and pharmacies located in or contracting with long-term care facilities will be required to provide that the pharmacy has between 30 and 90 days to submit claims for reimbursement.

For plan years beginning on or after January 1, 2009, contracts between pharmacies and PDP sponsors or MA-PD plans that use the cost of a drug as the standard for reimbursement of pharmacies will be required to provide that the sponsor update the standard at least every seven days, to accurately reflect the market price of acquiring the drug.

Public Disclosure of Prices

Part D sponsors are required to ensure that their network pharmacies inform enrollees of any price differential between a covered drug and the lowest price generic version of the drug that is therapeutically equivalent, bioequivalent, on the plan's formulary, and available at that pharmacy.

Privacy, Confidentiality, and Accuracy of Enrollee Records

Plans must abide by all applicable federal and state laws regarding confidentiality and disclosure of any medical records that it maintains. Further, it must maintain the records in an accurate and timely manner and ensure timely access by enrollees to records and information pertaining to them.

Grievances, Coverage Determinations, and Appeals

Part D plans are required to have procedures in place for handling grievances, for making timely coverage determinations, and for handling appeals of coverage determinations. They must ensure that all enrollees receive written information about these procedures.

Grievances. Grievances are complaints or disputes, other than those involving coverage determinations, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan, regardless of whether remedial action is requested. Grievances may include such things as complaints about the plan's customer service hours of operation, time to obtain a prescription, or pharmacy charges. A grievance may also include a complaint that the Part D plan refused to expedite a coverage determination or redetermination. A beneficiary with a grievance should file the complaint within 60 days of the event. The plan sponsor must respond on a timely basis.

Coverage Determinations. A coverage determination is any determination (either an approval or denial) made by the plan sponsor with regard to covered benefits. The following actions are considered coverage determinations:

- A decision about whether to provide or pay for a part D drug that the enrollee believes may be covered. This includes a decision not to pay because the drug is not on the plan's formulary, the drug is

determined not medically necessary, or the drug is furnished by an out-of-network pharmacy.

- Failure to provide a coverage determination in a timely manner when a delay would adversely affect the health of the enrollee.

- A decision concerning a tiering exceptions request. MMA provided that if a Part D plan includes a tiered cost-sharing structure, a plan enrollee can request an exception to the structure. Under an exception, a nonpreferred drug could be covered as a preferred drug if the prescribing physician determined that the preferred drug for treatment of the same condition would not be as effective for the individual, would have adverse effects for the individual, or both.

- A decision concerning a formulary exceptions request. MMA provided that a beneficiary enrolled in a Part D plan can appeal a determination not to provide coverage for a drug not on the plan's formulary. The appeal can only be made if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

- A decision on the amount of cost-sharing.

- A decision whether the individual has, or has not, satisfied a prior authorization or other utilization management requirement.

A request for a coverage determination may be filed by the enrollee, the enrollee's appointed representative, or the enrollee's physician. The sponsor must notify the enrollee of its determinations within 72 hours of receipt of the request (or, in the case of an exceptions request, receipt of the physician's supporting statement). An enrollee can request an expedited decision; if the plan approves the request, it must make the determination within 24 hours.

Appeals. If the plan's coverage determination is unfavorable to the enrollee, it must provide the enrollee with a written denial notice that includes information on appeals rights. There are five levels of appeals.

Redetermination. The first level of appeal is a redetermination by the plan. An enrollee, or the appointed representative, may request a standard redetermination with respect to covered drug benefits or payments. An enrollee, the appointed representative or the enrollee's prescribing physician may request an expedited redetermination for covered drug benefits. The request should generally be filed within 60 days of the unfavorable coverage determination. The sponsor must provide the enrollee or prescribing physician with a reasonable opportunity to present evidence. Enrollees must be notified of the results within seven days in the case of standard redetermination. Enrollees requesting expedited redeterminations of a request for covered drugs must be notified of the results within 72 hours, if the plan accepts the expedited request.

The redetermination must be made by a person not involved in the original coverage determination. If the issue is the denial of coverage based on medical necessity, the redetermination must be made by a physician.

Reconsideration by an Independent Review Entity. An enrollee dissatisfied with a redetermination has a right to reconsideration by an independent review entity (IRE) that contracts with CMS for this purpose. Currently, MAXIMUS Federal Services is the Part D IRE.

An enrollee or an enrollee's appointed representative may request a standard or expedited reconsideration. The request must be made within 60 days of the redetermination. An enrollee's prescribing physician may not request a reconsideration on an enrollee's behalf unless the enrollee's physician is also the enrollee's appointed representative. The IRE must solicit the views of the prescribing physician. It is required to make a decision within seven days for a standard reconsideration and 72 hours for an expedited reconsideration.

Administrative Law Judge. The third level of appeal is an administrative law judge (ALJ). An enrollee or the appointed representative may request a hearing with an administrative law judge. An enrollee's prescribing physician may not request a hearing by an ALJ on an enrollee's behalf unless the enrollee's physician is also the enrollee's appointed representative. The request must be made within 60 days of the IRE decision letter. To get an ALJ hearing, the projected value of denied coverage must meet a minimum dollar amount ($120 in 2008). No time frames are specified for ALJ action.

Medicare Appeals Council. The fourth level of appeal is the Medicare Appeals Council (MAC). A beneficiary or the appointed representative may request a review by the MAC within 60 days of the ALJ decision. The MAC may grant or deny the request for review. If it grants the request, it may issue a final decision or dismissal, or remand the case to the ALJ with instructions on how to proceed with the case. No times frames are specified for a MAC review.

Federal District Court. The final appeal level is a Federal district court. A beneficiary or the appointed representative may request a review by a federal court within 60 days of the MAC decision notice. To receive a review by the court, the projected value of denied coverage must meet a minimum dollar amount ($1,180 in 2008).

Cost Control and Quality Improvement

Part D sponsors are required to have a drug utilization management program, quality assurance measures and systems, and a medication therapy management program.

Drug Utilization Management. Sponsors must establish a reasonable and appropriate drug utilization management program that (1) includes incentives to reduce costs when medically appropriate and (2) maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

Quality Assurance. The sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. Such measures and systems must provide that network providers are required to comply with state standards for pharmacy practice. They must also provide both for concurrent drug utilization review systems and retrospective review systems.

Medication Therapy Management. Each Part D Sponsor is required to incorporate a Medication Therapy Management Program (MTMP) into their plans' benefit structure. Each year, sponsors are required to submit a MTMP description to CMS for review and approval. A CMS-approved MTMP is one of several required elements in the development of sponsor' bids for the upcoming contract year.

An approved MTMP must (1) ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use; (2) reduce the risk of adverse events for targeted beneficiaries; (3) be developed in cooperation with licensed and practicing pharmacists and physicians; (4) be coordinated with any care management plan established for a targeted individual under a chronic care improvement program; (5) describe the resources and time required to implement the program if using outside personnel and establish the fees for pharmacists or others. The MTMP may be furnished by pharmacists or other qualified providers and may distinguish between services in ambulatory and institutional settings.

Targeted beneficiaries under a MTMP are enrollees who have chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered drugs that exceed a level specified by the Secretary ($4,000 in 2008).

CMS has outlined additional expectations for MTMPs. Beneficiaries enrolled in a MTMP cannot be disenrolled later in the year, even if they no longer meet one of the eligibility criteria. Plans will provide interventions for beneficiaries meeting all of the criteria regardless of the setting. The plan will not include discriminatory exclusion criteria.

E-Prescribing

MMA required the development of electronic prescribing (e-prescribing) standards for the Part D program. The first (or "foundation") e-prescribing standards, which became effective in 2006, created uniform system requirements for several e-prescribing functions, such as eligibility and benefits queries between prescribers and Part D sponsors. In accordance with the MMA, CMS also conducted a pilot study to assess the feasibility of creating additional e-prescribing standards. On April 7, 2008, CMS issued final rule-making to adopt standards for transactions related to formulary and benefit information and medication history.

Providers and pharmacies are not required to use e-prescribing; however, a provider or pharmacy that does e-prescribe for Part D beneficiaries is required to comply with any applicable final standards that are in effect. Further, all Part D plans are required to maintain e-prescribing systems that conform to the final standards.

MIPPA included incentives for E-prescribing. For 2009 through 2013, Medicare professionals providing covered services to Medicare beneficiaries and who are successful electronic prescribers will receive an incentive payment of 2.0% for 2009 and 2010, 1.0% for 2011 and 2012, and 0.5% for 2013.

Payments to Plans

CMS makes four types of payments to Part D plans: (1) direct subsidy payments, (2) reinsurance payments, (3) low-income subsidy payments, and (4) risk-sharing payments.

Direct Subsidies

Medicare makes per capita monthly payments to plans for each Part D enrollee. The payment is equal to the plan's approved standardized bid amount, adjusted by the plan beneficiaries' health status and risk, and reduced by the base beneficiary premium for the plan.

Plan Bid. As noted earlier, plans are required to submit, not later than the first Monday in June, a bid for the following year. The bid is to include an estimate of its average monthly revenue requirements to provide qualified prescription drug benefits (including any supplemental coverage) for a Part D eligible individual with a national average risk profile. The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible. The bid is to exclude costs paid by enrollees, payments expected to be made by CMS for reinsurance and any other costs for which the sponsor is not responsible. CMS reviews the bids, negotiates with plans, and approves the bids.

National Average Monthly Bid Amount. CMS then computes a *national average monthly bid amount* from approved bids. This is to be a weighted average of the standardized bid amount for each prescription drug plan. For PDPs, the standardized bid amount is that portion of a plan's bid attributable to basic prescription drug coverage; for MA-PDs, it is the portion of the accepted bid that is attributable to basic prescription drug coverage.

In calculating the nationwide average, CMS is to weight each plan's bid by its share of total enrollment. In 2006, the first year of Part D, there was no prior PDP enrollment information; therefore each PDP plan was weighted equally (though MA-PD bids were enrollment weighted if they had 2005 MA enrollment). Rather than immediately moving to full enrollment weighting in 2007, CMS provided for a phase-in under its demonstration authority ("Medicare Demonstration to Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans"). In 2007, 80% of the national monthly bid amount was based on the 2006 averaging methodology and 20% on the enrollment weighted average. In 2008, 40% is based on the 2006 averaging methodology and 60% on the enrollment weighted average. CMS chose this phase-in approach because with 2006 enrollment heavily weighted toward lower cost plans, immediate use of the enrollment weighting

methodology would have resulted in lower direct subsidies, and by extension higher beneficiary premiums.

The calculation of the national average monthly bid amount does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs populations, PACE programs and plans established through reasonable cost contracts.

The national average monthly bid amount for 2007 was $80.43; it is $80.52 in 2008.

Payment to Plans. Individual plan bids are adjusted for expected case mix. This adjustment takes into account variation in costs among plans for basic coverage based on the differences in actuarial risk of different enrollees being served. Per capita monthly direct subsidy payments equal this adjusted amount minus the base beneficiary premium. (See discussion below for how beneficiary premiums are calculated.)

Reinsurance Subsidies

As noted in the discussion of prescription drug benefits, Part D plans pay all drug costs above the catastrophic threshold ($5,726.25 in 2008) except for nominal beneficiary cost-sharing.

Medicare subsidizes 80% of the plans' costs for catastrophic coverage. CMS makes reinsurance subsidy payments to plans in behalf of those individuals who have actually incurred such costs. Payments are made on a monthly basis during the year based on either estimated or incurred costs, with final reconciliation made after the close of the year.

In the case of private fee-for-service plans offering drug coverage, CMS determines reinsurance payments by basing the amount on CMS' estimate of the amount that would be paid if it were a coordinated care plan and takes into account average payments for populations of similar risk in such plans.

Risk Corridor Payments

MMA established risk corridors which were intended to limit a plan's overall risks or profits under the new program. By using risk corridors, Medicare is able to limit a plan's potential losses by financing some of the higher than expected costs. Similarly, Medicare is able to limit a plan's potential gains by recouping excessive costs. Over time, as more experience is gained with the program, the risk corridors are widened, thereby increasing the insurance risk borne by the plans. The risk corridor provisions do not apply to private fee-for-service plans.

Risk corridors are defined as specified percentages above and below a target amount. The target amount is defined as total payments paid to the plan, taking into account the amount paid by the CMS and enrollees, based on the standardized bid amount, risk adjusted, and reduced by total administrative expenses assumed in the

bid. No payment adjustments are made if adjusted allowable costs for the plan are at least equal to the first threshold lower limit of the first risk corridor but not greater than the first threshold upper limit of the risk corridor for the year (i.e., if the plans are within the first risk corridor). A portion of any plan spending above or below these levels is subject to risk adjustment. If adjusted allowable costs exceed the first threshold upper limit, then payments are increased. If adjusted allowable costs are below the first threshold lower limit, then payments are reduced. Adjusted allowable costs are reduced by reinsurance and subsidy payments. (See **Table 3**.)

During 2006 and 2007, plans were at full risk for adjusted allowable risk corridor costs between 2.5% below and 2.5% above the target. Plans with adjusted allowable costs above this level received increased payments. If their costs were between 2.5% of the target (first threshold upper limit) and 5% of the target (second threshold upper limit), they were at risk for 25% of the increased amount; that is, their payments equal 75% of adjusted allowable costs for spending in this range. If their costs were above 5% of the target they were at risk for 25% of the costs between the first and second threshold upper limits and 20% of the costs above that amount. That is, their payments equal 80% of the adjusted allowable costs over the second threshold upper limit. Conversely, if plans fell below the target, they shared the savings with the government. They have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 80% of any amounts below 5% of the target.

For 2008-2011, the risk corridors are modified. Plans are at full risk for drug spending between 5.0% below and 5% above the target level. Plans are at risk for 50% of spending exceeding 5.0% but below 10.0% of the target level. Additionally, they are at risk for 20% of any spending exceeding 10% of the target level. Conversely, if plans fall below the target, they have to refund 50% of the savings if costs fall between 5% and 10% below the target level and 80% of any amounts below 10% of the target. Beginning in 2012, CMS may increase the target levels above the 5% and 10% levels.

Table 3. Plan Liability Under Risk Corridor Provisions

Risk Corridor	Plan Liability for Costs Above and Below Target
2006-2007	
Costs below 95% of the target	80% refund
Costs between 95% and 97.5% of the target	75% refund
Costs between 97.5% and 102.5% of the target	Full risk
Costs between 102.5% and 105% of the target	Risk for 25% of amount
Costs over 105% of the target	Risk for 20% of amount
2008-2011	
Costs below 90% of the target	80% refund
Costs between 90% and 95% of the target	50% refund
Costs between 95% and 105 % of the target	Full risk
Costs between 105 % and 110 % of the target	Risk for 50% of amount
Costs over 110% of the target	Risk for 20% of amount

Low-Income Subsidy (LIS) Payments

CMS makes additional payments to plans on behalf of persons entitled to low income subsidies. These payments are for premium and cost-sharing charges which would otherwise be paid by the beneficiary except for the fact that they are entitled to subsidies. (See "Low-Income Individuals" section below).

Reconciliation

CMS makes prospective payments to plans based on their bids. Following the close of the calendar year, CMS makes retroactive adjustments to reflect actual plan experience. Prospective payments for reinsurance and low income subsidy payments are compared to actual incurred costs and other related data, and appropriate adjustments are made to the plan payments. The calculation is based on costs actually incurred and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates). Direct subsidy payments to the plans are adjusted to reflect updated data about beneficiary health status and enrollment. In addition, any necessary adjustments are made to reflect risk sharing under the risk corridor provisions.

In October 2007, CMS announced that it would collect $4 billion from Part D drug plan sponsors due to lower-than-expected drug costs in 2006. It stated that it would be collecting these funds from plans due to the fact that actual drug costs for almost all Part D plans were below expected levels in their 2006 bids. It cited several factors leading to lower spending, including the fact that 2006 marked the first time that plans were bidding on the new Part D program and the fact there were higher levels of generic drug utilization in Part D than had been anticipated. It further noted that plans submitted their bids for the 2006 contracting year in June 2005. The 2006 bids were therefore somewhat uncertain predictions of what would actually happen when the drug benefit began in 2006. CMS expects that as experience with Part D grows, plan bid submissions will more closely reflect actual costs. It stated that the 2007 bid submissions were significantly lower than those submitted in 2006 and were a reflection of the actual 2006 Part D drug program experience. Therefore, CMS anticipates that amounts collected from or paid to plans in future years as a result of final reconciliation and risk adjustment will be lower than that for the 2006 plan year.[8]

Beneficiary Premiums

Beneficiaries pay monthly premiums for Part D coverage. Payments vary by the plan selected. On average, beneficiary premiums are to represent roughly 25.5% of the cost of basic coverage.

[8] CMS, *Medicare Expects to Recover $4 Billion from Part D Plans Following 2006 Plan Reconciliation*, Press Release, October 5, 2007.

The monthly premium is uniform for all persons enrolled in the plan (except for those receiving low-income subsidies or those subject to a late enrollment penalty). It equals the base beneficiary premium, as adjusted to reflect the difference between the plan's standardized bid amount and the nationwide average bid.

Base Beneficiary Premium. The base beneficiary premium for a Part D plan equals the product of the beneficiary premium percentage and the national average monthly bid amount (see calculation under "Direct Subsidies," above). The beneficiary premium percentage is equal to 25.5%, divided by 100% minus a percentage equal to total reinsurance payments divided by the sum of such reinsurance payments and total payments the Secretary estimates will be paid to prescription drug plans in a year that are attributable to the standardized bid amount (taking into account amounts paid by CMS and enrollees).

The base beneficiary monthly premium was $27.35 in 2007 and is $27.93 in 2008.

Adjustments. Once the base beneficiary premium is calculated, it is adjusted up or down, as appropriate, to reflect any difference between the plan's standardized bid amount and the nationwide average bid amount. Thus, beneficiaries in plans with higher costs for standard coverage face higher than average premiums for such coverage, while enrollees in lower cost plans pay lower than average premiums for such coverage.

Premiums are further increased to reflect any supplemental benefits or any late enrollment penalty and decreased if the individual is entitled to a low-income subsidy. Additionally, enrollees in MA-PD plans may see a decrease if plans use rebates, based on Parts A and B benefit costs, to buy down the Part D premium.

Program Financing

Medicare Part D is financed through a combination of Federal general revenues, beneficiary premiums, and state contributions. Revenues are credited to a separate account, the Medicare Prescription Drug Account, in the Medicare Part B trust fund.

General Revenues and Beneficiary Premiums

General Revenues. General revenues are transferred from the Treasury to the Part D Account on an as-needed basis to support the portion of program expenditures funded by federal subsidies.

Beneficiary Premiums. Beneficiaries may have their premiums deducted from their social security or other federal benefit payments; these are then forwarded to Part D plans on their behalf. Alternatively, they can pay their premiums directly to the Part D plan. Both types of payments are shown in the statement of the Part D account in the annual Medicare trustees report.

State Contributions

Effective January 1, 2006, states are no longer providing coverage for Part D drugs for their dual eligible population under Medicaid. They could be expected to see a reduction in their Medicaid spending as a result of this transfer. However, MMA contained a provision (labeled by some as the "clawback provision") that requires states to continue to assume a portion of these costs. The formula specified in law is based on a proxy for what states would otherwise be spending on drugs for the dual eligibles in the absence of MMA. In 2006, states assumed 90% of these costs; over the next nine years the states' contribution phases-down to 75% in 2015.

Formula for State Contribution Amount. States are required to pay the Secretary each month an amount equal to the *product* of the following three factors:

- The projected monthly per capita drug payment which is product of: base year (2003) state Medicaid per capita expenditures for covered Part D drugs for full benefit dual eligible persons (reduced by any rebates received) and the current state matching rate. This amount is increased each year (beginning in 2004) by the applicable growth factor; beginning in 2007 this is the per capita percentage increase in Part D expenditures.

- Total number of full benefit dual eligibles for the state for the month.

- The applicable percentage factor (90% in 2006, 88 1/3% in 2007, 86 2/3 % in 2008, decreased each year by 1 2/3 percentage points until 2015 and later when it is 75%).

Impact on States. A review for the National Association of State Medicaid Directors found that most states report that the combination of the transition of dual eligibles to Part D coupled with state clawback payments have not resulted in significant state savings. Only 10 states reported paying less in 2007 for dual eligibles than when the state provided drugs directly to this population. Further, most states have not implemented wrap-around coverage for Part D cost-sharing amounts for low-income subsidy beneficiaries.[9]

Part D Account Data

MMA created a separate Part D account within the Medicare Part B trust fund. The 2007 Medicare Trustees Report stated that in calendar year 2006, total Part D revenues were $48.1 billion. This included $3.5 billion in beneficiary premiums, $39.1 billion in government contributions, $5.5 billion in state contributions and $13 million interest on investments. Total Part D benefits (including employer subsidy payments) were $47.3 billion with an additional $0.3 billion for federal administrative expenses. (See **Table 4**.)

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[9] National Association of State Medicaid Directors, *2007 State Perspectives - Medicaid Pharmacy Policies and Practices*, November 2007.

The trustees reported that the 2006 expenditures were less than had been predicted in the 2005 and 2006 trustees report. They attributed this change to several factors including a slowdown in the growth in prescription drug spending; the fact that savings from retail discounts, manufacturer rebates, and utilization management were achieved in 2006 rather than over several years as had been previously assumed; and the fact that significantly fewer beneficiaries joined the program than initially anticipated and that some who joined enrolled after the beginning of the year.

Table 4. Statement of Operations of Part D Account, Calendar Year 2007
(in millions)

Total Assets at Beginning of Year	$687.0
Revenues	**$52,118.3**
Premiums from Enrollees	3,775.1
Premiums deducted from social security checks	1,628.1
Premiums paid directly to plans	2,147.0
Government Contributions	**41,349.4**
Prescription drug benefits	40,332.6
Administrative expenses	1,016.8
Payments from States	6,977.5
Interest on Investments	16.4
Expenditures	**$52,213.3**
Benefit Payments	51,208.8
Federal Administrative Expenses	1,004.5
Assets of fund at End of Year	**$592.1**

Source: Table V.F3., 2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds.

Note: Totals may not add due to rounding.

Employer Subsidies

MMA included provisions designed to encourage employers to continue to offer drug benefits to their Medicare-eligible retirees. It provided a subsidy for a portion of retiree drug costs and exempted these subsidy payments from federal taxes.

Qualifications

Qualified Plans. CMS makes the subsidy payments to employers or unions offering qualified retiree prescription drug coverage. Qualified plans are defined as those offering drug benefits at least actuarially equivalent to "standard coverage."

Qualifying Covered Retiree. Subsidy payments are made on behalf of an individual covered under the retiree health plan who is entitled to enroll under a PDP or MA-PD plan but elects not to. Subsidies are linked to an individual's status as a retired participant in the qualified group health plan or as the Medicare-enrolled spouse or dependent of the retired participant. Thus, a sponsor offering qualified coverage for dependants will be able to claim coverage for a Part D eligible dependent of a retired participant, even if the retiree is under age 65 and not Part D eligible. However, the sponsor will not be able to claim coverage for a Part D eligible dependent of an active employee.

An individual retiree can elect to enroll in Part D, even if the former employer has elected to take the subsidy. However, this decision may have consequences. It is possible the individual could lose employer-sponsored drug coverage or both employer-sponsored medical and drug coverage. Further, any payments made by the employer plan would not count toward meeting the true out-of-pocket (TROOP) requirements (See earlier discussion of Part D benefits.)

Subsidy Benefits

Subsidy payments equal 28% of a retiree's gross drug costs between specified levels ($275-$5,600 in 2008). The dollar amounts are adjusted annually by the percentage increase in Medicare per capita prescription drug costs.) Subsidy payments to employers and unions are not subject to federal tax.

Alternatives

Employers or unions may select an alternative option (instead of taking the subsidy) with respect to Part D. They may elect to pay a portion of the Part D premiums. They may also elect to provide enhanced coverage that may be provided through supplementary or "wrap around" benefits. This approach may have some financial consequences for the employer or union since third party payments do not count toward TROOP. Thus, if an employer chooses to pay some of the Part D cost-sharing on behalf of its retirees, this would have the effect of delaying the point at which the Part D catastrophic coverage would begin. The employer could therefore end up paying some costs which would otherwise be covered under the catastrophic portion of the Part D benefit.

Employers or unions may also contract with a PDP or MA-PD to offer the coverage. Finally, they may become a Part D plan sponsor themselves for their retirees.

Subsidy Data

Employer Actions. A December 2006 survey by Kaiser Family Foundation and Hewitt[10] noted that its survey of 302 large private-sector firms with 1,000 or more employees showed that the majority of plan sponsors (78%) would seek the

[10] The Henry J. Kaiser Family Foundation and Hewitt, *Retiree Health Benefits Examined - Findings from the Kaiser/Hewitt 2006 Survey on Retiree Health Benefits*, December 2006.

subsidy in 2007 (compared with 82% in 2006). Six percent said they were likely to supplement the benefit; another 6% said they intended to contract with a PDP or MA-PD to offer additional coverage, and 2% said they intended to become a PDP. Eight percent said they were likely to discontinue prescription drug coverage.

Retirees Covered. In January 2008, the Secretary of HHS announced that 6.7 million persons were in retiree plans receiving a subsidy. An estimated 1.5 million were in plans with coverage at least as good as Medicare's but without a subsidy. Further, an estimated 2.0 million beneficiaries were in TRICARE and the Federal Employees Health Benefits program (FEHB); the federal government elected not to take the employer subsidy for these individuals on the grounds that it would be merely subsidizing itself.

Issues

In January 2008, Part D began its third year of operation. While early start-up issues have generally been resolved, some issues remain. The following highlights a few of these.

Low-Income Individuals

A major focus of Part D is the enhanced coverage provided to low-income individuals through the low-income subsidy (LIS) program. Despite extensive federal, state, and local outreach efforts, not all persons potentially eligible have enrolled in the program. As of January 2008, CMS estimated that 2.6 million persons eligible for LIS had neither signed up for Part D nor had coverage through another source. It is not immediately clear why some individuals have failed to enroll, though several factors, including a lack of program awareness and the nature of the application process itself play a role. The assets limitations are viewed by some as being too low, thereby precluding otherwise eligible persons from gaining coverage.

A second issue of concern to the low-income population is the large number of persons required to change plans each year because the premium for their current plan no longer falls below the low-income subsidy level. Some observers have suggested that when making the low-income subsidy calculation (see earlier discussion) the MA-PD enrollment should be removed from the calculation. Their inclusion in the calculation has the effect of lowering the benchmark, thereby forcing a higher number of persons enrolled in PDPs to change plans if they are to remain in zero premium plans.

High-Income Enrollees

On average, beneficiary premiums account for 25.5% of expected total Part D costs for basic coverage; federal general revenues account for most of the remaining costs. Some persons have suggested that higher income persons should pay a higher percentage of their costs. Except for persons entitled to low-income subsidies, all persons selecting a particular Part D plan pay the same monthly premium amount.

The President's FY2009 Budget proposal (together with the subsequent legislative proposal submitted in response to the Medicare trigger requirement)[11] would establish income-related premiums for Part D. The percentage increases would be tied to the benchmark premium amount for basic coverage. The add-on amount (also referred to as the subsidy reduction) would be the same regardless of the particular plan selected by the beneficiary. The total amount that a beneficiary would pay in Part D premiums would be the add-on amount (which would be the same nationwide) plus the premium for the particular plan selected (which would vary by plan).

Under the proposal, the income thresholds would be the same as those currently established for income-relating Part B premiums and therefore affect the same people. Further, as proposed for Part B (in the FY2009 Budget, but not included in the proposed trigger legislation), the income thresholds would not be updated in future years. Consequently, each year the number of beneficiaries subject to the higher premium would increase.

The Administration estimated that this provision would save $350 million in FY2009 and $3.18 billion over the five-year budget period. An estimate of the number of beneficiaries who would be affected by higher premiums was not provided. At the time the 2008 Part B premiums were announced in October 2007, CMS estimated that about 5% of beneficiaries would be affected by the income-related premium increase in 2008. It is thought that a slightly lower percentage would be affected by the Part D proposal; this is because some high-income Medicare beneficiaries have alternative sources of prescription drug coverage (such as through a former employer) and therefore do not enroll in Part D.

Some observers (who had also opposed income-relating the Part B premium) suggest that this approach would further move Medicare from its entitlement nature.

Beneficiary Experience

When MMA was enacted, few observers expected beneficiaries to have a choice among so many drug plans. Some argue that the large number of plans available to beneficiaries may complicate their choices. Given that enrollment tends to be heavily concentrated in plans offered by a limited number of sponsors, it is likely that the number of available options will decline over time.

Beneficiaries have tended to enroll in plans with low premiums, and zero or low deductibles. However, in the absence of concrete data, it is not clear whether this is always the best choice for the beneficiary.

Most Part D enrollees did not change plan enrollment from 2006 to 2007. As noted in the "key facts section" below, premiums for the most popular plans rose in 2008; plan sponsors may also have made other changes including changing

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[11] See CRS Report RL34407, *The President's Proposed Legislative Response to the Medicare Funding Warning*, by Hinda Chaikind, Jim Hahn, Jennifer O'Sullivan, and Henry Cohen.

copayments or utilization controls for particular drugs. Despite the fact that plans are required to notify beneficiaries of changes, it is not clear how many are aware of the year-to-year modifications. CMS reports 3.1 million Part D enrollees or about 12% of the total changed plans from 2007 to 2008. Of those, 2.1 million were LIS beneficiaries who were reassigned so they would not have to pay a premium. About 6% of non-LIS beneficiaries made a change.

At this point, information is not available to assess the impact of Part D over time on changes in drug utilization patterns and out-of-pocket costs.

Drug Prices

Noninterference Clause. Some observers have recommended striking the noninterference provision in the law. They claim that permitting CMS to be involved in negotiating drug prices would result in additional savings. Other observers state that plans are already achieving price reductions. The Congressional Budget Office has stated that removal of the noninterference clause would be unlikely to achieve significant additional savings, particularly if CMS were not allowed to establish a formulary or use other tools to reduce prices.[12]

Data. A considerable amount of plan-specific data is available on the WEB. However, certain information (for example, information dealing with price trends or price concessions such as rebates) is proprietary. The gaps in data have made it difficult to provide a complete picture of the program's impact.

This issue has been addressed by both CMS and MIPPA. On May 27, 2008, the CMS issued a final rule that would allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. Some organizations that submitted comments on the rule questioned the CMS's authority to use the Part D data for other than payment purposes. MIPPA grants CMS authority to use and share data from Part D. As a result of this modification, information provided to the Secretary in the administration of Part D may be used for the purposes of improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate), and shall be made available to congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

Pharmacies

Plans have not been not required to process claims within a specified time period. Thirty days has been considered the standard, though some pharmacies, particularly those located in rural areas allege that some claims have taken up to 45 days. They stated that claims should be paid within 14 days. Some observers stated

[12] Congressional Budget Office, *S. 3, Medicare Prescription Drug Price Negotiation Act of 2007*, cost estimate, April 16, 2007.

that some pharmacies, particularly small pharmacies, are unable to handle the lag and are being driven out of business. As noted earlier, MIPPA addresses these concerns by requiring prompt payment of pharmacy claims. Beginning in 2010, clean claims submitted electronically must be paid within 14 days and other clean claims paid within 30 days.

Key Part D Facts

Enrollment

Enrollment by State. The annual open enrollment period for 2008 closed December 31, 2007. As of January 2008, approximately 25.4 million Medicare beneficiaries were enrolled in PDP and MA-PD plans. An additional 6.7 million beneficiaries had prescription drug coverage through a former employer that is receiving a federal subsidy for a portion of such coverage. Approximately 7.5 million beneficiaries had drug coverage through another source including persons with Federal Employees Health Benefits (FEHB) coverage and TRICARE coverage. An estimated 4.6 million or 10% of Medicare beneficiaries had no drug coverage. **Table 5** shows the nationwide distribution of Medicare enrollees by the source of drug coverage.

Table 5. Total Number of Medicare Beneficiaries with Drug Coverage, as of January 2008

(in millions)

Medicare Beneficiaries Eligible for Part D	**44.20**
Medicare Part D	**25.40**
Stand Alone PDP	17.39
MA with Drug Coverage	7.63
Other Plan Types	0.38
Medicare Retiree Drug Subsidy (RDS)	**6.66**
Other Drug Coverage	**7.53**
TRICARE	0.90
FEHB Retiree Coverage	1.05
Veterans Affairs Coverage	1.59
Active Workers with Medicare Secondary Payer	1.20
Multiple Sources of Creditable Coverage	0.69
Retiree Coverage (not RDS)[a]	1.54
Medigap and Other Individual Insurance[a]	0.21
State Pharmaceutical Assistance Programs[a]	0.02
Indian Health Service Coverage[a]	0.03
Other Sources[a]	0.30
Total Beneficiaries with Drug Coverage	**39.59**

Source: CMS, January 2008. [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp].
Note: An estimated 4.6 million persons or 10% of beneficiaries had no drug coverage.

a. Information only available at the national level.

Table 6 shows the January 2008 state-by-state distribution of the 37.5 million persons (shown in **Table 5**) with drug coverage through Part D, a former employer receiving the employer subsidy, or other coverage through FEHB, TRICARE, VA or as an active worker. State-by-state breakdowns are not available for 2.1 million persons receiving certain other types of coverage (as noted in Table 5).

Table 6. State Enrollment in Prescription Drug Plans

(as of January 2008)

State	Part D Eligible	Stand-Alone Prescription Drug Plan[a]	Medicare Advantage with Prescription Drugs[b]	Medicare Retiree Drug Subsidy	Other Prescription Drug Coverage[c]	Total with Coverage
Alabama	794,170	329,711	116,564	126,876	118,076	691,227
Alaska	57,827	22,914	254	14,421	9,740	47,329
Arizona	848,034	217,315	290,550	100,910	119,399	728,174
Arkansas	499,571	255,092	43,026	50,213	78,021	426,352
California	4,407,441	1,585,286	1,420,472	427,935	411,197	3,844,890
Colorado	564,253	165,071	161,290	75,569	83,833	485,763
Connecticut	540,170	225,473	63,980	111,588	58,386	459,427
Delaware	137,191	64,772	2,717	33,301	16,959	117,749
District Of Columbia	74,239	27,858	5,927	3,952	21,506	59,243
Florida	3,151,715	1,022,527	796,646	450,681	442,241	2,712,095
Georgia	1,123,763	554,151	102,623	125,930	166,875	949,579
Hawaii	190,515	62,693	60,579	7,739	31,409	162,420
Idaho	208,283	85,041	31,700	23,232	32,629	172,602
Illinois	1,752,798	853,431	110,729	337,611	175,214	1,476,985
Indiana	947,458	444,989	49,484	194,281	105,444	794,198
Iowa	501,508	291,116	37,513	40,178	63,040	431,847
Kansas	412,783	220,467	27,639	32,346	64,387	344,839
Kentucky	715,037	343,395	52,482	127,600	82,469	605,946
Louisiana	644,114	277,145	109,435	87,347	72,691	546,618
Maine	248,248	135,976	6,972	21,977	34,305	199,230
Maryland	730,525	270,136	43,944	142,301	146,730	603,111
Massachusetts	1,003,321	391,598	168,292	185,272	103,268	848,430

State	Part D Eligible	Stand-Alone Prescription Drug Plan[a]	Medicare Advantage with Prescription Drugs[b]	Medicare Retiree Drug Subsidy	Other Prescription Drug Coverage[c]	Total with Coverage
Michigan	1,551,570	505,869	252,875	441,554	112,230	1,312,528
Minnesota	735,812	299,812	188,510	76,182	81,211	645,715
Mississippi	471,110	283,253	18,408	29,390	71,045	402,096
Missouri	952,110	423,524	150,867	118,545	122,205	815,141
Montana	157,265	74,953	14,013	14,805	26,288	130,059
Nebraska	268,451	151,994	20,601	24,212	39,949	236,756
Nevada	321,668	82,341	95,315	40,447	52,437	270,540
New Hampshire	200,348	84,879	4,279	35,655	30,782	155,595
New Jersey	1,266,002	542,470	105,541	280,248	131,319	1,059,578
New Mexico	287,395	115,172	60,113	23,907	44,874	244,066
New York	2,860,851	988,173	620,818	544,471	249,742	2,403,204
North Carolina	1,368,169	635,716	161,955	212,726	166,444	1,176,841
North Dakota	105,405	69,800	4,142	4,707	15,419	94,068
Ohio	1,812,939	589,569	300,878	508,943	167,722	1,567,112
Oklahoma	568,388	271,304	59,212	51,753	93,456	475,725
Oregon	571,135	185,639	173,284	46,409	75,393	480,725
Pennsylvania	2,195,478	701,874	618,352	310,740	242,701	1,873,667
Rhode Island	175,877	58,471	57,165	12,372	23,717	151,725
South Carolina	702,584	309,484	64,168	118,745	108,935	601,332
South Dakota	129,969	75,633	9,904	6,565	23,221	115,323
Tennessee	980,209	449,574	164,442	112,748	120,593	847,357
Texas	2,735,037	1,136,370	386,680	423,741	389,432	2,336,223
Utah	256,511	90,721	46,262	31,345	46,172	214,500
Vermont	102,652	55,151	678	18,251	13,408	87,488

State	Part D Eligible	Stand-Alone Prescription Drug Plan[a]	Medicare Advantage with Prescription Drugs[b]	Medicare Retiree Drug Subsidy	Other Prescription Drug Coverage[c]	Total with Coverage
Virginia	1,055,919	453,431	78,413	119,199	222,513	873,556
Washington	881,153	339,831	114,449	117,497	133,373	705,150
West Virginia	368,891	165,538	54,021	55,886	43,931	319,376
Wisconsin	860,935	315,760	114,550	135,683	92,867	658,860
Wyoming	74,689	38,090	2,370	7,735	13,600	61,795
Other[d]	627,358	51,825	365,161	15,211	59,109	491,306
Total	**44,198,844**	**17,392,378**	**8,010,244**	**6,660,930**	**5,451,907**	**37,515,459**

Source: CMS Management Information Integrated Repository (MIIR) as of January 18, 2008, at [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp].

a. Includes 5.3 million beneficiaries who were auto-enrolled and 2.6 million additional beneficiaries receiving the low-income subsidy.
b. Includes 1.3 million beneficiaries who were auto-enrolled and .15 million additional beneficiaries receiving the low-income subsidy.
c. Includes FEHB, TRICARE, VA, and Active Workers.
d. Other includes beneficiaries in the territories and whose address information is being updated.

Table 7 shows the distribution, as of January 2008, of the approximately 12.5 million enrollees who are eligible for the low-income subsidy (LIS). An estimated 9.38 million persons are receiving the assistance. Another 0.5 million have coverage through another source. An estimated 2.6 million persons are thought to be eligible for LIS, but were not enrolled. **Table 8** shows the state-by-state distribution of the approximately 9.4 million enrollees receiving LIS.

Table 7. LIS-Eligible Medicare Beneficiaries With Drug Coverage

(as of January 2008)

Description	Total LIS-Eligible Beneficiaries (millions)
Total Beneficiaries Eligible for Low-Income Subsidy	**12.50**
Less: Drug Coverage from Medicare	**9.38**
CMS-Deemed-Full Dual Eligibles	6.18
CMS Deemed-MSP and SSI Recipients	1.67
LIS Approved and Not Deemed	1.53
Less: Drug Coverage from Former Employer (RDS)	**0.04**
Less: Additional Sources of Creditable Drug Coverage	**0.42**
Veterans Affairs (VA) Coverage	0.39
Indian Health Service Coverage	0.03
Less: Anticipated Facilitated Enrollments	**0.06**
TOTAL Remaining LIS-Eligible Beneficiaries	**2.60**

Source: [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp]
(CMS Office of the Actuary (eligible estimate based on updated SIPP survey data); CMS Management Information Integrated Repository (MIIR) (as of Janaury 18, 2008); Department of Veterans Affairs; Indian Health Service)

Notes: Remaining LIS-eligible category may include some LIS-eligible beneficiaries who have not yet regained their deemed status or who have been approved for the LIS, but are still receiving drug coverage through Medicare Part D. This category may also include some LIS-eligible beneficiaries who have not yet applied for the LIS.

Table 8. LIS-Eligible Medicare Beneficiaries with Medicare Part D Coverage, by State

(as of January 2008)

State	CMS-Deemed Full Dual Eligibles	CMS-Deemed MSP and SSI Recipients	LIS Approved and Not Deemed	TOTAL LIS
Alabama	88,887	95,505	39,481	223,873
Alaska	12,115	393	1,615	14,123
Arizona	104,190	28,410	18,459	151,059
Arkansas	63,857	40,854	27,519	132,230
California	1,045,340	20,612	85,650	1,151,602
Colorado	52,714	18,342	20,249	91,305
Connecticut	67,189	21,265	11,369	99,823
Delaware	10,109	10,427	3,596	24,132
District Of Columbia	15,664	2,427	2,457	20,548
Florida	298,101	199,111	91,344	588,556
Georgia	138,611	93,760	58,015	290,386
Hawaii	25,738	2,701	6,642	35,081
Idaho	19,510	7,807	7,587	34,904
Illinois	242,841	34,485	60,531	337,857
Indiana	86,108	45,372	38,321	169,801
Iowa	57,227	11,125	14,077	82,429
Kansas	38,704	13,569	15,195	67,468
Kentucky	146,711	5,202	40,845	192,758
Louisiana	95,327	61,170	30,720	187,217
Maine	47,817	30,967	2,728	81,512
Maryland	61,931	30,240	29,533	121,704
Massachusetts	207,019	14,517	21,739	243,275
Michigan	195,288	24,847	48,672	268,807
Minnesota	97,753	12,525	15,370	125,648
Mississippi	74,379	60,703	24,917	159,999
Missouri	134,988	22,725	37,210	194,923
Montana	13,200	5,575	6,435	25,210
Nebraska	32,528	3,330	7,890	43,748
Nevada	20,407	15,398	11,053	46,858
New Hampshire	18,463	6,216	6,822	31,501
New Jersey	152,026	25,356	45,516	222,898
New Mexico	34,821	20,556	11,745	67,122
New York	558,058	72,987	90,680	721,725
North Carolina	219,955	49,397	69,914	339,266
North Dakota	9,901	3,392	4,202	17,495
Ohio	184,301	71,410	58,494	314,205
Oklahoma	80,796	17,003	24,383	122,182
Oregon	54,126	24,704	16,477	95,307
Pennsylvania	277,684	47,558	69,214	394,456

State	CMS-Deemed Full Dual Eligibles	CMS-Deemed MSP and SSI Recipients	LIS Approved and Not Deemed	TOTAL LIS
Rhode Island	30,036	4,533	6,512	41,081
South Carolina	114,149	16,580	39,249	169,978
South Dakota	11,926	5,793	4,216	21,935
Tennessee	186,085	60,311	38,273	284,669
Texas	340,961	187,090	152,521	680,572
Utah	23,722	3,184	6,766	33,672
Vermont	17,403	6,668	1,639	25,710
Virginia	104,805	46,348	48,567	199,720
Washington	101,462	26,578	21,095	149,135
West Virginia	42,372	25,623	19,109	87,104
Wisconsin	111,919	11,921	14,463	138,303
Wyoming	5,825	2,702	2,354	10,881
Other[a]	5,004	2,638	1,771	9,413
Total	**6,180,053**	**1,671,912**	**1,533,201**	**9,385,166**

Source: [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp]
(CMS Management Information Integrated Repository (MIIR), as of January 18, 2008).

a. Includes information from the territories and for beneficiaries whose address information is being updated.

Plan Enrollment.[13] Part D enrollment is highly concentrated. In 2007, two organizations, UHC-PacifiCare and Humana, captured more than 40% of all Part D enrollees. These two organizations had the largest number and share of Part D enrollees in both stand-alone PDPs and MA-PDs. The top four organizations (including Wellpoint, Inc. and Member Health Inc.) captured 54% of enrollment. The top 10 organizations captured 72%. All of the top 10 organizations offered multiple plans, and all but Kaiser Permanente offered both stand alone PDP and MA-PD plans.

In 2007, 13% of Part D enrollees were in AARP's Medicare Rx Plan (offered by UHC-PacifiCare). This figure actually represented a decline from 2006, possibly because some persons shifted to a lower premium AARP offering, the AARP Medicare Savers Plan, which was also one of the top 10 plans, in terms of enrollment.

Humana sponsored three of the top 10 plans in 2007. The two PDP offerings, in second and third place, captured 9% and 5% of the market. Enrollment in its private fee-for-service plan increased significantly from 2006, because of a dramatic increase in market offerings.

[13] The Henry J.Kaiser Family Foundation, *Overview of Medicare Part D Organizations, Plans and Benefits by Enrollment in 2006 and 2007*. November 2007.

Plan Features.[14] In 2007, only 14% of enrollees were in plans offering the defined standard Part D benefit. Half (51%) were enrolled in plans that offered actuarially equivalent benefits, while 35% were in plans that provided an enhanced benefit. Over three-quarters (79%) of enrollees in MA-PD plans had enhanced benefits, while only 21% of PDP enrollees had such coverage. Over half of PDP enrollees were in plans with no deductible, while almost all of MA-PD enrollees had no deductible.

In 2007, 85% of enrollees were in plans with no gap coverage; 12% had coverage for some generics in the gap, and 3% had coverage for both brand name and generic drugs in the gap. Eight of the top 10 plans offering both generic and brand coverage in the gap were MA-PD plans. One PDP (SierraRxPlus PDP) offering full gap coverage in 2007 is not offering such coverage in 2008.

It should be noted that low-income enrollees receiving LIS assistance have partial or full subsidized coverage in the gap. This group represents close to 40% of enrollees. When both those with LIS assistance and some gap coverage are taken into account, approximately half of enrollees (49%) had no gap coverage in 2007.

2008 Plan Overview

Table 9 provides an overview of PDP plan offerings for 2008. The number of plan offerings ranges from 47 in Alaska to 63 in West Virginia and Pennsylvania. The number of plans with premiums below the low income benchmark or with gap coverage is significantly lower.

Table 9 shows a wide range in premiums for PDP plans. Plans with higher premiums typically offer broader coverage. It should be noted that while essentially the same plan may be offered in a number of PDP regions (or nationwide) the premiums for the plan are not likely to be the same in all PDP regions.

When comparing plans, it is important to review a number of factors including the breadth of the formulary, the tier particular drugs are placed on, the cost sharing amounts applicable by tier, utilization tools, and the extent of gap coverage. Premiums for 2008 plans with gap coverage generally are twice that for plans without gap coverage.

[14] Ibid.

Table 9. Stand-Alone PDPs: Characteristics, by State, 2008

State	Number of Plans	Number Below Low-Income Benchmark	Some Gap Coverage[a]	Monthly Premium	
				Low	High
Alabama	53	15	15	$18.00	$98.00
Alaska	47	15	14	$14.70	$99.50
Arizona	51	7	15	$9.80	$99.50
Arkansas	55	18	16.	$13.00	$98.00
California	56	9	15	$14.30	$102.70
Colorado	55	12	16	$15.60	$99.50
Connecticut	51	14	15	$14.60	$99.50
Delaware	52	18	15	$16.10	$97.50
District of Columbia	52	18	15	$16.10	$97.50
Florida	58	8	18	$12.10	$97.50
Georgia	54	18	15	$16.60	$97.50
Hawaii	49	10	15	$13.70	$99.50
Idaho	54	14	15	$17.10	$99.50
Illinois	53	19	15	$17.70	$97.50
Indiana	52	17	15	$17.30	$98.00
Iowa	52	16	16	$13.90	$99.00
Kansas	52	17	15	$14.90	$99.50
Kentucky	52	17	15	$17.30	$98.00
Louisiana	50	10	14	$14.30	$97.50
Maine	53	18	16	$14.80	$99.50
Maryland	52	18	15	$16.10	$97.50
Massachusetts	51	14	15	$14.60	$99.50
Michigan	55	17	16	$17.90	$97.50
Minnesota	52	16	16	$13.90	$99.00
Mississippi	49	15	14	$17.50	$97.50
Missouri	52	13	15	$17.20	$97.50
Montana	52	16	16	$13.90	$99.00
Nebraska	52	16	16	$13.90	$99.00
Nevada	53	5	15	$12.10	$99.50
New Hampshire	53	18	16	$14.80	$99.50
New Jersey	57	18	18	$14.80	$98.50
New Mexico	55	11	16	$10.40	$97.50
New York	55	15	15	$16.70	$107.50

State	Number of Plans	Number Below Low-Income Benchmark	Some Gap Coverage[a]	Monthly Premium	
				Low	High
North Carolina	52	17	16	$14.50	$98.00
North Dakota	52	16	16	$13.90	$99.00
Ohio	58	15	17	$16.60	$98.00
Oklahoma	52	13	15	$16.40	$98.50
Oregon	55	15	17	$14.80	$101.60
Pennsylvania	63	18	17	$15.40	$99.00
Rhode Island	51	14	15	$14.60	$99.50
South Carolina	56	20	15	$15.40	$99.00
South Dakota	52	16	16	$13.90	$99.00
Tennessee	53	15	15	$18.00	$98.00
Texas	56	15	16	$12.10	97.50
Utah	54	14	15	$17.10	$99.50
Vermont	51	14	15	$14.60	$99.50
Virginia	52	17	15	$15.10	$98.00
Washington	55	15	17	$14.80	$101.60
West Virginia	63	18	17	$15.40	$99.00
Wisconsin	57	16	17	$14.10	$99.50
Wyoming	52	16	16	$13.90	$99.00

a. One PDP in Florida covers all generics and some brand name drugs. In other states "some gap coverage" includes plans covering all generics, all preferred generics, or some generics.

Sources: CMS, *State Data Fact Sheet Source, 2008*; The Henry J.Kaiser Family Foundation. *Medicare: Part D Plan Characteristics by State, 2008*, October 2007.

The average monthly PDP premium, weighted by enrollment, was $25.93 in 2006, $27.39 in 2007, and was projected to rise to $31.99 in 2008 (presuming beneficiaries did not switch plans).[15]

Part D enrollees typically do not switch plans from year to year. Preliminary analyses suggest that PDP enrollees who did not switch plans between 2007 and 2008 would likely see a premium increase. One analysis noted that if beneficiaries did not switch plans, three-quarters of those not receiving a low-income subsidy would see a premium increase. Nearly one in five (19%) would see a monthly increase of more than $10. Further, one-fourth of enrollees who did not switch from 2006-2008 would face a premium increase of at least 50% over the period.[16]

[15] The Henry J. Kaiser Family Foundation. *Medicare Part D 2008 Data Spotlight: Premiums*. November 2007.

[16] Ibid.

High premium increases are recorded for the two PDPs with the highest enrollment. The average annual premium for AARP's Medicare Rx Plan (offered by UHC-PacifiCare) increased from $316 in 2006 to $388 in 2008. The average annual premium for Humana PDP Standard increased from $114 to $310 in 2008.[17] The increase in United's premium means that it lost its autoenrollment of the low-income subsidy population in 18 out of 34 regions.[18]

Cost Estimates

The CBO March 2008 baseline estimates total Part D benefit payments at $45.5 billion in FY2008, $54.3billion in FY2009, rising to $138.4 billion in FY2018. (See **Table 10**.)

Table 10. Part D Benefit Payments, Selected Years

(estimate in billions of dollars)

Payments	FY2008	FY2009	FY2018
Payments to Plans	25.1	32.2	82.7
Retiree Drug Subsidy	3.2	3.3	7.4
Low-Income Subsidy	17.1	18.8	48.3
Total Benefit Payments	**$45.5**	**$54.3**	**$138.4**

Source: CBO, Fact Sheet for CBO's March 2008 Baseline: Medicare.
Note: Totals may not add due to rounding.

[17] Ibid.

[18] Avalere Health LLC. *CMS Release of Part D Plan "Landscape" for 200*8, September 28, 2007.