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Medicare Prescription Drug Benefit: Low-Income Provisions

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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 Part D, effective January 1, 2006. Medicare beneficiaries are able to purchase drug coverage through private plans offered by prescription drug plan (PDP) sponsors or managed care organizations offering Medicare Advantage prescription drug (MA-PD) plans. These private plans bear some of the financial risk for drug costs. Federal subsidies covering the bulk of the risk are provided to encourage participation in these private plans.

MMA required PDP sponsors and MA-PDP plans 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 actuarially equivalent benefits (i.e., having at least equivalent dollar value). In both cases, access must be provided to negotiated prices for drugs. Beneficiaries are required to pay a monthly premium for program coverage as well as certain cost-sharing charges when they obtain benefits.

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

Implementation of the new program, particularly for the low-income population, has proved challenging. Observers cited a number of problems that arose when the dual eligible population was transferred from Medicaid to Medicare coverage on January 1, 2006. The Centers for Medicare and Medicaid Services (CMS) took a number of actions designed to address the problems that arose immediately after the shift became effective. While some of the initial problems have been somewhat mitigated, many administrative issues remain.

More recently, attention has also focused on other low-income persons eligible for subsidy assistance. As of early May 2006, CMS estimated that 3.2 million out of a total of 13.2 million persons eligible for low-income subsidies had neither signed up for Part D nor had coverage through another source. The Administration therefore took two major actions designed to increase enrollment among this target population. First, it stated that *persons deemed eligible for a low-income subsidy after the close of the initial enrollment period on May 15, 2006, can still enroll in a Part D plan in 2006.* Second, *these late enrollees will not be subject to the late enrollment penalty otherwise applicable to persons who miss the enrollment deadline.*

This report provides background information on the MMA provisions, program implementation, and related state issues. It 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 Part D, effective January 1, 2006.[1] Medicare beneficiaries are able to purchase drug coverage through private plans offered by prescription drug plan (PDP) plan sponsors or managed care organizations offering Medicare Advantage prescription drug (MA-PD) plans. These private plans bear some of the financial risk for drug costs. Federal subsidies covering the bulk of the risk are provided to encourage participation.

MMA requires PDP sponsors and MA-PDP plans 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 actuarially equivalent benefits (i.e., having at least equivalent dollar value). In both cases, access must be provided to negotiated prices for drugs. Beneficiaries are required to pay a monthly premium for program coverage as well as certain cost-sharing charges when they obtain benefits.

A major focus of MMA is the enhanced coverage provided to low-income individuals who enroll in Part D. Low-income enrollees, *including those who previously received drug benefits under Medicaid,* have their prescription drug costs paid under the new Part D. Persons with incomes below 150% of poverty have assistance with some portion of the premium and cost-sharing charges. Persons with the lowest incomes have the highest level of assistance. MMA represents the first time that the level of Medicare benefits is tied to income.[2]

Effective January 1, 2006, Medicaid no longer covers drug costs for persons eligible for both Medicare and Medicaid (i.e., the "full benefit dual eligible" population). State Medicaid spending is reduced as a result of this transfer of responsibility. However, the law contains a provision (labeled by some as the

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[1] For an overview of MMA, see CRS Report RL31966, *Overview of the Medicare Prescription Drug, Improvement and Modernization Act of 2003,* by Jennifer O'Sullivan, Hinda Chaikind, Sibyl Tilson, Jennifer Boulanger, and Paulette Morgan.

[2] MMA also provided for higher Medicare Part B premiums for high-income enrollees, beginning in 2007. The increase was to be phased in over five years. However, the Deficit Reduction Act of 2005 (DRA) shortened the phase-in to three years. See CRS Report RL32582, *Medicare: Part B Premiums,* by Jennifer O'Sullivan.

"clawback provision") which requires states to continue to assume a portion of these costs.

The Centers for Medicare and Medicaid Services (CMS, the agency that administers Medicare) issued final regulations implementing the MMA drug provisions on January 28, 2005.[3] Subsequently, CMS has issued a number of guidance documents to further clarify a number of issues related to implementation of the low-income provisions.

Implementation of the new program, particularly for the low-income population, has proved challenging. Observers cited a number of problems that arose when the dual eligible population was transferred from Medicaid to Medicare coverage on January 1, 2006. CMS took a number of actions designed to address the problems that arose immediately after the shift became effective.

More recently, attention has also focused on other low-income persons eligible for subsidy assistance. Many observers were concerned that this population might not be identified and enrolled on a timely basis. The Administration took two major actions to address this concern. First, it stated that *persons deemed eligible for a low-income subsidy after the close of the initial enrollment period on May 15, 2006, can still enroll in a Part D plan in 2006.* Second, *these late enrollees will not be subject to the late enrollment penalty otherwise applicable to persons who miss the enrollment deadline.*

This report begins by providing an overview of MMA benefits, including premium and cost-sharing liabilities for the general Medicare population. The overview is followed by a discussion of the subsidy benefits available for low-income individuals. The report then highlights some of the key implementation issues.

MMA Benefits

All Medicare beneficiaries are entitled to obtain qualified prescription drug coverage through enrollment in a private prescription drug plan under the new Medicare Part D.[4] Persons enrolled in a Medicare Advantage (MA) plan providing qualified prescription drug coverage obtain coverage through that plan. Other individuals obtain coverage through enrollment in a plan offered by a PDP sponsor. Beneficiaries who elect to enroll in a plan are responsible for a monthly premium, which varies by the individual plan selected. At the time of enactment, the Congressional Budget Office (CBO) estimated that in 2006, Part D plan premiums would average $35. In March 2006, CMS estimated monthly plan premiums at $25 (about 25% of the total cost of the benefit).

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[3] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Medicare Program; Medicare Prescription Drug Benefit;* Final rule, 70 *Federal Register* 4193, Jan. 25, 2005.

[4] See CRS Report RL33136, *Medicare: Enrollment in Medicare Drug Plans*, by Jennifer O'Sullivan.

MMA requires PDP sponsors and MA-PD plans 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 actuarially equivalent benefits (i.e., having at least equivalent dollar value). In both cases, access must be provided to negotiated prices for drugs.

For 2006, the "standard prescription drug coverage" is defined as follows:

- $250 deductible paid by the beneficiary;
- 75% of costs paid by the program and 25% of costs paid by beneficiary up to the initial coverage limit ($2,250, accounting for $750 in total out-of pocket costs and $2,250 in total spending);
- 100% of costs paid by beneficiary for drug spending falling in the coverage gap between $2,251 and $5,100 (accounting for total beneficiary out-of-pocket spending of $3,600); and
- all costs paid by program over $5,100 in total spending (the "catastrophic" trigger) except for nominal beneficiary cost-sharing defined as the greater of: (1) a copayment of $2 for generic drug or preferred multiple source drug and $5 for other drugs; or (2) 5% coinsurance.

Beginning in 2007, the annual dollar amounts are to be 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.

MMA specifies that beneficiaries must incur a certain level of out-of-pocket costs ($3,600 in 2006) 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.

Low-Income Provisions

MMA provides assistance to certain low-income persons to help them meet Part D premium and cost-sharing charges. Specifically, such assistance is provided for persons with incomes below 150% of the federal poverty level and assets below specified amounts. The definitions of income and assets are linked directly or indirectly to the definitions used under current Medicaid law. The law specifies several low-income coverage groups and subgroups. Each low-income coverage group specified by MMA receives a different level of assistance.

The specified assistance for low-income groups is linked to "standard prescription drug coverage." Each low-income group receives assistance for premium and cost-sharing charges otherwise applicable under standard coverage. Persons with the lowest incomes have the highest level of assistance.[5]

The following specifies the requirements applicable for each low-income eligibility group and outlines the assistance available for each group.

Eligibility Groups

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:

Group 1, referred to as 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; and (3) have resources in 2006 below $6,000 for an individual and $9,000 for a couple (increased in future years by the percentage increase in the consumer price index, or CPI).

The following groups of persons are also included in Group 1.

- *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 Group 1, regardless of whether they meet the other eligibility requirements.

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

- *Enrollees in Medicare Savings Programs*. MMA permitted the Secretary to extend Group 1 coverage to enrollees in Medicare Savings Programs. (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

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[5] It should be noted that the law permits plans to offer the general population "actuarially equivalent" benefits. They are also permitted to impose tiered cost-sharing for the general population, that is cost-sharing percentages which vary by whether the drug is generic or brand or preferred or not preferred. Most plans offered in 2006 are for "actuarially equivalent" benefits. However, cost-sharing for the low-income population can not exceed the lower of: (1) the specific limits specified for the low-income under standard coverage (as discussed later in this report), or (2) the amount otherwise charged to the general population.

(QMBs)[6], (2) specified low-income Medicare beneficiaries (SLIMBs)[7], and (3) qualifying individuals (QI-1s).[8,9]

Group 2, referred to as Other Subsidy Eligible Individuals. Group 2 includes all other persons who (1) are enrolled in a PDP plan or MA-PD plan; (2) have incomes below 150% of poverty; and (3) have resources in 2006 below $10,000 for an individual and $20,000 for a couple (increased in future years by the percentage increase in the CPI).[10]

Definition of Income and Assets. The definitions of income and assets generally follows that used for determining eligibility under the QMB, SLIMB, 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 which 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 specifies 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.

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[6] QMBs are aged or disabled persons with incomes at or below the federal poverty level. In 2006, the monthly level is $837 for an individual and $1,120 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.

[7] SLIMBs meet the QMB criteria, except that their income is between 100% and 120% of the federal poverty level. In 2006, the monthly income limits are $1,000 for an individual and $1,340 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.

[8] 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 2006, the monthly income limit for QI-1 for an individual is $1,123 and for a couple $1,505. Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium.

[9] An additional Medicare savings group is Qualified Disabled and Working Individuals (QDWIs); individuals in this group may have income up to 200% of the federal poverty level. Unlike the other Medicare Savings groups, this group is entitled to no special treatment under the low-income subsidy provisions of Part D.

[10] It should be noted that some publications have cited assets levels of $11,500 and $23,000; these number include a $1,500 per person burial allowance.

- *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, SLIMB, and QI-1 programs. A few states have elected this option. As noted above, MMA permits the Secretary to include all persons meeting QMB, SLIMB, and QI-1 criteria in Group 1; the Secretary elected to do so. However, only persons on QMB, SLIMB, 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.

Low-Income Subsidy Benefits

MMA provides subsidies for both premiums and cost-sharing charges under Part D.

Premium Subsidies. All persons in Group 1 (i.e., full subsidy-eligible individuals) receive a premium subsidy equal to 100% of the low-income benchmark premium amount (essentially a weighted average for the region), but in no case higher than the actual premium amount for standard 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 individuals in Group 1 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.

All persons in Group 2 (i.e., other subsidy eligible individuals) have a sliding scale premium subsidy ranging from 100% of the low-income benchmark 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.

Persons in Group 1, but not Group 2, 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.

Cost-Sharing Subsidies. Cost-sharing subsides are linked to "standard prescription drug coverage." Beneficiaries in Group 1 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 for a generic drug prescription or preferred multiple source drug prescription and $3 for any other drug prescription. All other persons in Group 1 have cost-sharing, for all costs up to the out-of-pocket threshold, of $2 for a generic drug or preferred multiple source drug and $5 for any other drug.[11] (See **Table 1**.)

Beneficiaries in Group 2 have a $50 deductible, 15% coinsurance for all costs up to the out-of-pocket limit, and cost-sharing for costs above the out-of-pocket threshold of $2 for a generic drug prescription or preferred multiple source drug prescription and $5 for any other drug prescription. (See **Table 1**.)

Each year, beginning in 2007, the cost-sharing amounts for full benefit dual eligibles below 100% of poverty will be increased by the increase in the CPI. The cost-sharing amounts for all other persons, and the deductible amount for Group 2, will be increased by the annual percentage increase in per capita beneficiary expenditures for Part D covered drugs.

[11] The preamble to the final CMS regulations notes that MA-PD plans can not choose to eliminate the copayments for dual eligible individuals, except in the case of specialized MA plans (under Section 231 of MMA) offering benefits only to dual eligible individuals.

Table 1. Part D Benefits, 2006

(by per capita drug spending category)

Total drug spending (dollar ranges)	All beneficiaries		Low-income			
			Group 1		Group 2	
	Paid by Part D	Paid by enrollee	Paid by Part D	Paid by enrollee	Paid by Part D	Paid by enrollee
$0-$250	0	$250	$250	0	$200	$50
$250.01-$2,250	75%	25%	100% less enrollee cost-sharing	Institutionalized duals: $0 Duals under 100% of poverty: $1/$3[b] Others: $2/$5[c]	85%	15%
$2,251-$5,100	0	100%	100% less enrollee cost-sharing	Institutionalized duals: $0 Duals under 100% of poverty: $1/$3[b] Others: $2/$5[c]	85%	15%
$5,100.01 and over	95%[a]	5%	100%	0	100% less enrollee cost-sharing	$2/$5[c]

Source: P.L. 108-173, §§ 1860D-2 and 1860D-14.

a. Assumes enrollee has met true out-of-pocket (TROOP) threshold of $3,600.
b. $1 per prescription for generic or preferred drugs that are multiple source drugs; $3 per prescription for other drugs.
c. $2 per prescription for generic or preferred drugs that are multiple source drugs; $5 per prescription for other drugs.

Uncovered Drug Expenditures. It should be noted that low-income individuals are entitled to cost-sharing subsidies only for drugs included on a plan's formulary. No subsidies are available for costs for drugs not on the formulary of the individual's plan unless such individual has successfully appealed to have coverage granted for a particular drug. As is the case for all such appeals (for both the low-income and other persons), an individual can make such an appeal only 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 state Medicaid program cannot "wrap around" the Part D benefit unless it chooses to fund 100% of the costs. Federal matching is not available to cover the costs of any drug which could be included under Part D but is excluded under a particular plan's formulary.

Medicaid can continue to provide coverage (and receive federal matching payments) for drugs specifically excluded from coverage under Part D. Included in this category are benzodiazepines and barbiturates.

Territories

The low-income subsidies are available for persons residing in the 50 states and the District of Columbia. While residents of the territories[12] may enroll in a PDP under Part D, they are not entitled to the low-income subsidies. Instead, a territory may submit a plan to the Secretary for providing drug coverage for its low-income population. Each territory with an approved plan can receive a grant based on its ratio of Medicare beneficiaries in the territory compared to the number in all territories. The total amount of funding available is $28.125 million in the last three quarters of FY2006, $37.5 million in FY2007, increasing in subsequent years by the percentage increase in prescription drug spending for Medicare beneficiaries.

Early Program Implementation: Process and Issues

Eligibility and Enrollment Procedures

In order to take advantage of the low-income subsidies, an individual must be determined eligible for the assistance *and* be enrolled in a Part D plan. A separate process is established for each. In general, applications for the subsidy and enrollment in a Part D plan can occur in any order. The procedures for establishing eligibility and enrolling in a plan are outlined below. It should be noted that in certain cases different rules apply for different subcategories of the low-income population.

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[12] American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands.

In general, current Medicare enrollees had to enroll with a Part D plan by the close of the initial enrollment period on May 15, 2006. Failure to do so meant that these individuals could not enroll until the open enrollment period for 2007 (November 15, 2006-December 31, 2006), with coverage beginning January 1, 2007. Further, these persons would be subject to a late enrollment penalty if they went for more than 63 days without creditable drug coverage (namely, coverage at least as good as standard Part D coverage.

However, both the 2006 closing date and application of the late enrollment penalty for persons deemed eligible for a low-income subsidy after May 15, 2006, have been waived.

Eligibility for Low-Income Subsidies. Certain groups are automatically deemed full subsidy-eligible individuals; other persons have to apply for assistance.

Deemed Individuals. Persons automatically deemed full subsidy-eligible individuals are full benefit dual eligibles, QMBs, SLIMBs, QI-1s, and recipients of SSI. These individuals must be notified that they are deemed eligible for a full subsidy for a period up to one year. Further, they are to be informed that they do not need to apply for the subsidy. Persons who were enrolled in one of these programs in 2005 were to be notified prior to January 1, 2006, that they qualified for the subsidy.

Other Persons. Other individuals (or their personal representatives) have to apply for subsidy assistance. Applicants may apply either at state Medicaid offices or Social Security offices. Applicants are required to provide information from financial institutions, as requested, to support information in the application, and to certify as to the accuracy of the information provided.

State Medicaid programs are required to make eligibility determinations for persons applying to the state Medicaid agency. The Commissioner of the Social Security Administration (SSA) is required to make such determinations for persons applying at SSA offices. No specific time frame is established for these determinations. Redeterminations and appeals are to be handled by the same agency making the initial determination.

Applications to SSA may be filed in person, by mail, by phone, or over the Internet. CMS encouraged states to use the SSA application form when assisting beneficiaries and to forward these application forms to SSA. SSA processes these applications and is responsible for associated redeterminations and appeals. However, states are still required to have the ability to make such determinations for individuals who request them to do so.

Plan Enrollment Process. In general, Medicare beneficiaries voluntarily enroll in a PDP or MA-PDP plan during the initial enrollment period (November 15, 2005-May 15, 2006), during an initial seven-month enrollment period (for persons becoming eligible on or after March 1, 2006), the annual open enrollment period (November 15-December 31 each year), or, in certain exceptional cases (such as involuntary loss of other drug coverage), during a special enrollment period. A new

special enrollment period has been established for certain low-income persons. (See below.)

Auto-enrollment for Dual Eligible Beneficiaries. Special provisions apply for full benefit dual eligible individuals. Effective January 1, 2006, these persons could no longer receive Medicaid coverage for drugs covered under Part D. The law required automatic enrollment for dual eligibles who fail to enroll in a PDP or MA-PDP plan. Individuals are to be enrolled with the plan in the region that has a premium not exceeding the premium subsidy amount. If more than one such plan is available, enrollment among these plans is made on a random basis. Individuals are to be informed in advance of the selected plan. Nothing prevents an individual from declining such enrollment or disenrolling from the plan in which they have been enrolled and enrolling in a different plan. Further, dual eligibles can change plan enrollment at any time, with enrollment in the new plan effective the following month.

Auto-enrollment was to occur in the fall of 2005 for persons on the Medicaid rolls at that time; enrollment was effective January 1, 2006.[13] CMS randomly assigned full benefit dual eligible beneficiaries in original Medicare to PDP plans with premiums at or below the low-income premium subsidy amount. Special rules applied in the case of MA enrollees. These persons were assigned to a MA-PD plan with the lowest premium offered by the same MA organization, even if the plan's monthly prescription drug premium exceeded the low-income premium subsidy amount. Beneficiaries were to be informed in advance of the assignment. If the beneficiary failed to affirmatively select another plan or declined Part D enrollment, he or she was to be considered to be enrolled in the assigned plan.

Other Enrollees. MMA limited the requirement for auto-enrollment to full benefit dual eligibles. It did not apply to the Medicare Savings population or to other persons eligible for low-income subsidies. However, CMS established a process, labeled "facilitated enrollment" for enrollees in Medicare Savings programs (MSPs), SSI enrollees, and persons who have applied for and been approved for low-income subsidy assistance. The basic features applicable to auto-enrollment for dual eligibles (i.e., random assignment, assignment to a plan with the lowest premium, and assignment of MA enrollees to lowest cost MA-PD plan offered by the MA organization) are extended to facilitated enrollment.

Facilitated Enrollment Process. Initially, CMS intended to conduct the facilitated enrollment process after the close of the open enrollment period on May 15, 2006. If an individual did not select a plan during the open enrollment period, the person would be enrolled in a plan, effective June 1, 2006. However, in March 2006, CMS announced that beneficiaries eligible for facilitated enrollment were being sent notices in early April informing them of the plans they would be enrolled in if they took no action before April 30, 2006. If the beneficiary failed to select another plan (and did not decline Part D enrollment), he or she would be considered

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[13] For duals newly eligible for Part D after that date, enrollment is effective on the first day of the month the individual becomes eligible for Part D.

to be enrolled in the assigned plan. The effective date of plan enrollment would be May 1, 2006.

One notice was to be sent to persons identified as qualifying for a full subsidy, while a different notice was to be sent to those qualifying for a partial subsidy. Those qualifying for a partial subsidy are liable for a portion of the plan's premium; the plan is to bill the beneficiary directly for the amount.

CMS stated that some persons would not be sent a facilitation notice. Included were persons whose former employer or union plan sponsor was claiming the retiree drug subsidy on their behalf.[14] In addition, CMS worked with state pharmacy assistance programs in five states (New York, New Jersey, Connecticut, Pennsylvania, and Illinois) to make sure that any persons the state planed to enroll in a Medicare drug plan would also not have facilitated enrollment by CMS.

Special Enrollment Periods. The law and regulations establish special enrollment periods (SEPs) outside of the general enrollment periods, during which an individual can disenroll from one PDP or MA-PD and enroll in another one.

In General. Generally, an individual can only take advantage of a SEP under special circumstances, such as moving from one part of the country to another. However, low-income enrollees who have been auto-enrolled or whose eligibility into a plan has been facilitated can have additional SEPs. Full benefit dual eligibles, as well as MSP enrollees, can change enrollment at any time, with the coverage change effective the following month. Other persons whose eligibility into a plan has been facilitated may change their enrollment once prior to the annual open enrollment period, with enrollment effective the following month.[15]

Special Enrollment Period for Low-Income Subsidy Eligible Individuals. Recently, CMS established a special enrollment period for persons eligible for a low-income subsidy.[16] (It characterized the change in status resulting from a low-income subsidy determination made after May 15 as an exceptional circumstance warranting a special enrollment period.)[17] Specifically, *persons deemed eligible for a low-income subsidy after the close of the initial enrollment period on May 15, 2006, can still enroll in a Part D plan in 2006*. The President subsequently stated that *these late enrollees will not be subject to the late enrollment penalty otherwise applicable to persons who miss the 2006 enrollment deadline.*[18]

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[14] See CRS Report RL33041, *Medicare Drug Benefit: Retiree Provisions*, by Jennifer O'Sullivan.

[15] Originally only full benefit dual eligibles were to be allowed to switch plans monthly. Recently this policy was extended to all MSP enrollees.

[16] CMS, Center for Beneficiary Choices, *Instructions for 2007 Contract Year*, memorandum to Medicare Prescription Drug Plan (PDP) Sponsors, Apr. 3, 2006.

[17] U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, Statement of Mark McClellan, Administrator of CMS, May 3, 2006.

[18] The White House, *President Bush Discusses Medicare Prescription Drug Benefit*, (continued...)

Eligibility and Enrollment Issues

Dual Eligibles.[19] On January 1, 2006, more than 6 million dual eligibles were to be transitioned from Medicaid to Medicare drug coverage. The auto-enrollment process was intended to prevent any coverage gap.

Initial Start-Up. Prior to January 1, 2006, many observers were concerned that the auto-enrollment process might not go smoothly. They noted that not all beneficiaries were correctly identified and enrolled in a plan. They also were concerned that many individuals might not be aware of the transition and/or might not know which plan they were enrolled in.

In December 2005, CMS established a backup process for any dual eligible arriving at a pharmacy without necessary documentation. The process included establishing several contractual relationships for the following activities: (1) establishing a new electronic eligibility inquiry (E1) system for pharmacists; (2) providing a point-of-sale (POS) contractor to pay claims for dual eligibles who were not immediately identified as enrolled in a PDP; and (3) hiring an enrollment contractor to work with drug plans and pharmacists to follow up on dual eligibles who were not enrolled in a plan, and to ensure that claims were billed to the appropriate parties. CMS also required Part D plans to develop and implement transition policies for individuals whose previously covered drugs were not on the plan's formulary. (See the discussion below).

Despite the establishment of the auto-enrollment and backup processes, the program experienced a number of problems during the initial days of operation — particularly related to the transition of dual eligibles. There were a number of reports about individuals who were unable to fill prescriptions because eligibility could not be verified or the drug plan's transition policies were not applied. Pharmacists also reported difficulty in getting timely and accurate information from the Medicare toll-free line, the PDP customer service representatives, and the newly established E1 system. Subsequently, CMS released additional guidance for drug plans and pharmacists, and dedicated additional resources to try and resolve these issues.

State and Federal Transition Funding. During the first weeks of 2006, 32 states stepped in temporarily to pay for drugs for dual eligibles who would otherwise have had a gap in coverage due to transition problems. CMS announced that the federal government would reimburse states for costs incurred prior to March 8, 2006;[20] with some states receiving extensions to March 31, 2006; CMS extended

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[18] (...continued)
transcript, Kings Point Clubhouse, Sun City Center, Florida, May 9, 2006.

[19] See CRS Report RL33268, *Medicare Prescription Drug Benefit: An Overview of Implementation for Dual Eligibles*, by Jennifer O'Sullivan and Karen Tritz, and CRS Report RS21837, *Implications of the Medicare Prescription Drug Benefit for Dual Eligibles and State Medicaid Programs*, by Karen Tritz.

[20] CMS used Section 402 demonstration authority; this is Section 402 of the Social Security (continued...)

the deadline for associated administrative costs to May 5, 2006. As of that date, CMS reported that it was working with a contractor to process claims and reconcile with plan sponsors in order to begin reimbursing states.[21] Some states have complained about the reimbursement delay. In addition, California, which has a large dual eligible population, has extended stop-gap coverage through the end of the year (with state-only funding) to address continuing problems encountered by beneficiaries.

Ongoing Issues. Reportedly, the number of dual eligibles experiencing difficulties with Part D has been reduced. However, some individuals continue to encounter problems. Some dual eligibles were enrolled in more than one plan. In many cases, this occurred when a beneficiary who had been auto-enrolled in one plan switched to another plan; in many cases the first plan still had the individuals on its rolls. CMS issued guidance to plans on March 21, 2006, on what was labeled the enrollment reconciliation process. This multi-step process was intended to assure that beneficiaries are enrolled in only one plan, that the plan they are enrolled in is their chosen plan, and that no beneficiary has a gap in coverage due to the reconciliation process. Part of the reconciliation process involves sending letters to beneficiaries who continue to have claim activity against the first plan. (Beneficiaries who have no claim activity against the original plan will be disenrolled from the plan, but will not be sent the letters.) The letters inform the individual that they are being disenrolled from the first plan unless they declare their intent to stay with that plan.

Enrollment for Other Low-Income Persons. As noted above, CMS moved the facilitated enrollment process up by a month. The goal was to try to avoid some of the problems that occurred in the auto-enrollment process and to correct any problems that might occur prior to the May 15, 2006 deadline. Subsequently, CMS waived the enrollment deadline for this population group.

A key concern is the identification of low-income persons eligible for subsidy assistance who are not enrolled in Medicare Savings Programs or SSI. SSA sent out letters to persons it identified as being possibly eligible for assistance. However, beneficiary advocates are concerned that many persons who should apply are either not aware of the benefit, do not understand the application process, or think they will not qualify.

On the other hand, the fact that an individual has received a letter from SSA does not automatically mean that an individual is eligible for a subsidy. SSA reported that as of April 30, 2006, it had received applications from 4.9 million beneficiaries; of these, almost 850,000 were unnecessary because either the applicants were automatically eligible or because they had filed more than one

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[20] (...continued)
Act of 1967 (P.L. 90-248), as amended.

[21] U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, Statement of Mark McClellan, Administrator of CMS, May 3, 2006.

application. The agency had made more than 3.9 million determinations; 1.7 million of these were deemed to be subsidy-eligible.[22]

Many observers contend that the relatively low percentage of eligibles reflects the program's assets limitations.[23] A number of persons have therefore suggested that the assets requirements should be eliminated. This would expand the pool of persons eligible for federal assistance. At the time of enactment, CBO estimated that 1.8 million otherwise eligible persons would not qualify for the subsidy because of the assets limitations. A report prepared for the Kaiser Family Foundation in April 2005 estimated that 2.37 million persons would not be eligible due to assets tests.[24] Of course, eliminating the assets test would also increase federal costs for the low-income subsidy.

Complicating the issue is the fact that individuals in a few states might be subsidy-eligible if they applied through their state's Medicaid office rather than through SSA. Both the states and SSA can make subsidy eligibility determinations; however, CMS encouraged states to both use the SSA application forms and to forward such forms to the SSA for action. States and SSA are to apply the same criteria for determining eligibility for low-income subsidies. However, some states use more generous methodologies for determining eligibility for Medicare Savings programs. As noted earlier, Medicare Savings recipients are automatically deemed eligible for full subsidy benefit. In the preamble to the final regulations, CMS acknowledged that there might be cases where an individual applies to the SSA for a low-income subsidy, is denied coverage because of excess income and assets, and is unaware that he or she might qualify for a full subsidy because of meeting the more generous Medicare Savings program requirements in the person's state.

The law and regulations provide that individuals can request that the state Medicaid office make the determination. When states make eligibility determinations they are also required to screen for eligibility for Medicare Savings programs. A separate section of the law (added before passage of MMA) requires SSA to annually identify individuals potentially eligible for Medicare Savings programs and transmit the information to the states.

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[22] U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, Statement of Beatrice Disman, Chairman Medicare Planning and Implementation Task Force, Social Security Administration, May 3, 2006.

[23] MMA established a temporary drug discount card program as a stop gap measure before the drug benefit was implemented on January 1, 2006. One feature of the discount card was a transitional $600 annual benefit in 2004 and 2005 for low-income persons. There were no assets tests for the $600 subsidy. It is therefore possible that some persons that were eligible for the drug card subsidy are not eligible for the low-income subsidy.

[24] Thomas Rice and Katherine Desmond, "Low-Income Subsidies for the Medicare Prescription Drug Benefit: The Impact of the Asset Test," *The Henry J. Kaiser Family Foundation*, Apr. 2005.

Plan Assignment

CMS assigned full benefit dual eligible beneficiaries to plans with premiums at or below the low-income premium subsidy amount. Similar assignments were made for other subsidy eligible enrollees who did not select a plan. The assignment process had the effect of directing the low-income population into the lower cost plans. Some observers contend that such plans may not in all cases be the ones the low-income individual would prefer based on the plan's formulary, pharmacy network, or other factors.

Some persons have suggested that the auto-enrollment and facilitated enrollment process should not be completely random, since low-income individuals often represent a more medically fragile population than Medicare beneficiaries as a whole. Some persons had recommended that enrollments be targeted toward an individual beneficiary's particular circumstances. However, CMS did not attempt to assign beneficiaries to a particular plan based on the individual's particular drug needs, pharmacy affiliation, or on their classification as a special needs population. CMS cited both data limitations and its inability to make individual selections, given the varied reasons for choosing a plan. Further, CMS had noted that full benefit dual eligibles and MSP enrollees may change plan enrollment at any time, while other low-income subsidy eligibles may change enrollment once before the end of the year.

Other Administrative Issues

Technology issues and data transfer lag times have been to blame for many of the problems facing the program's early implementation. Some of the problems included discrepancies between state and CMS files on the dual eligible population, delays in tracking which plan a beneficiary was enrolled in, and not making available on a timely basis the low-income subsidy status of enrollees, which led pharmacies to charge beneficiaries incorrect cost-sharing charges. While some of the problems have eased, many data transmission issues remain. One issue of particular concern for the low-income population is that when beneficiaries switch plans, their enrollment in the new plan is not recorded on a timely basis. CMS is encouraging plan switches to be made at the beginning of the month to allow more time for the change to be processed for the first day of the following month.

CMS also issued a memorandum on May 5, 2006, acknowledging "numerous complaints concerning full benefit dual eligible beneficiaries being charged incorrect copayments at the pharmacy." CMS outlined the following approaches to plans to correct this problem. First, plans are to use the best available data when they have knowledge that the beneficiary's cost-sharing level is not correct. Second, they must update their systems on a timely basis to reflect new information. Finally, plans are encouraged to reimburse pharmacies directly (rather than beneficiaries) when implementing retroactive subsidy changes, since is unlikely that the pharmacies had actually billed the beneficiaries for the charges.[25]

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[25] CMS, Center for Beneficiary Choices, *Incorrect Cost Sharing Charges to Dual Eligible Beneficiaries*, memorandum to Part D Plan sponsors, May 5, 2006.

Drug Formularies and Transition Coverage

PDs and MA-PDs have drug formularies. Formularies are lists of drugs that the plans will cover. Within broad guidelines, plans have considerable flexibility in designing their formularies. MMA required formularies to cover at least two drugs in each therapeutic category and class. The law also requested the United States Pharmacopeia (USP) to develop a list of categories and classes which could be used by plans in developing these formularies. The USP developed model guidelines, though not all PDs and MA-PDs follow the model. Plans may also incorporate utilization management tools such as prior authorization or step therapy (where a lower cost drug is first tried before a higher-cost drug may be approved).

Any individual enrolled in a plan may appeal to obtain coverage for a drug not on the formulary only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for the treatment of the same condition would not be as effective for the individual, would have adverse effects for the individual, or both.

The scope of a plan's formulary is particularly important for low-income beneficiaries who are generally unable to afford drugs not covered by the plan. A key implementation issue was what would happen to dual eligibles who previously had their drugs paid for by Medicaid. Many of these individuals were likely to be enrolled in plans that did not cover all of the drugs on their existing drug regimen. In response to these concerns, CMS developed policies relating both to the scope of plan formularies and transition rules.

Scope of Coverage. Many of the dual eligibles fall into one or more population subgroups, such as the mentally ill, the disabled, and those with HIV/AIDS. The drug regimens for these individuals are often very finely tuned to meet the needs of individual patients. Advocates for these populations note that successful treatments are often arrived at only after trying several different kinds of medications. They suggest that shifting individuals who have stabilized on one medication to another medication could have negative consequences, both medical and emotional. For example, advocates for the mentally ill stated that psychotropic drugs are not interchangeable. In addition, they note that if persons are forced to change regimens, some may experience increased hospitalizations and emergency room visits, thereby driving up overall medical costs.

CMS responded to this concern by requiring plan formularies to cover all or substantially all of the drugs in the following six categories: antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant, and HIV/AIDS. Further, CMS stated that its review of plan formularies includes a review of actual drugs to assure no discrimination against certain populations.

However, many dual eligibles were enrolled in plans that did not cover all of the drugs on their existing drug regimen. In January 2006, the Office of the Inspector General (OIG) of the Department of Health and Human services conducted a review

of drug plan formularies.[26] Of the top 200 drugs most commonly used by the dual eligible population in 2005, 178 are eligible for PDP coverage and 22 are excluded (see below). The OIG noted that this population group was being assigned to 409 PDPs that use 37 unique formularies. Nineteen percent of the formularies included all 178 of the Part D eligible drugs, while an equal proportion included less than 85%.

The OIG noted that under the random assignment process, 18% of dual eligibles were assigned to plans that included all 178 drugs, while 30% were assigned to plans that covered less than 85% of such drugs. However, every PDP region had at least one plan using a formulary that included all 178 drugs. Therefore, all dual eligibles have the opportunity to switch to plans including all of these drugs.

The OIG report was based on its analysis of the random enrollment process. Reportedly, many dual eligibles have subsequently switched plan enrollment. It is not known at this time what percentage of enrollees switched to plans with broader formulary coverage.

Transition Policies. CMS established transition policies intended to assure that new plan enrollees did not abruptly lose coverage for their drugs when they switched from Medicaid to Medicare. The regulations and initial CMS guidance documents required all plans to establish a transition process for new enrollees whose current drug therapies were not included in the plan's formulary. Based on this guidance, PDPs developed various transition policies. Generally, a minimum 30-day period was established, with many plans providing a 90-day period for long-term care facility residents. During this period, plans were to provide a temporary supply of non-formulary drugs.

During the initial start-up period, there were reports of many dual eligibles being unable to fill their prescriptions. CMS responded by requiring all PDPs to extend the transition period for all of these individuals through March 2006. During this period, PDPs were to help beneficiaries work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request a formulary exception if medically necessary. As the extended transition period ended, CMS reminded plans that they must provide beneficiaries with the appropriate assistance. Reportedly, many plans were responding to the end of the March transition period by phasing in their formularies gradually, thereby enabling them to manage their exceptions and appeals requests.

CMS stated that it was holding plans accountable for meeting their contractual requirements for resolving exceptions and appeals. It noted that it was monitoring plan performance, and stated its expectation that plans would provide a temporary supply when they were unable to meet established time frames. CMS further noted

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[26] U.S. Department of Health and Human Services, Office of Inspector General, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, Report OEI-05-06-00090, Jan. 2006.

that it would be imposing corrective actions, including sanctions, if enrollees were unable to obtain needed drugs on a timely basis.[27]

In April 2006, CMS announced the transition process requirements for 2007, which include the minimum standards plans are required to meet. Specifically, plans will be 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.)[28]

Formulary Changes. Many observers had expressed concerns that plans could change their formularies during the year, provided they gave 60 days' notice. Beneficiaries might have selected an individual plan based on its coverage of a particular drug, which might be subsequently dropped from the list.

On April 26, 2006, CMS provided a guidance document to Part D plan sponsors outlining its approach to formulary plan changes during a plan year.[29] The guidance document noted that both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the plan year. Generally, plans could expand formularies, modify therapeutic categories and classes only to account for new therapeutic uses and newly approved drugs, and make formulary maintenance changes.

The guidance document stated that plans could make other formulary changes, such as removing drugs from the formulary, moving drugs to a less preferred tier status, or adding utilization management requirements only in accordance with specified procedures. *The document further stated that plans should make such formulary changes during the year only if enrollees currently taking the affected drugs are exempted from the change for the remainder of the plan year.* CMS stated its expectation that plans would continue to comply with this policy in 2007 and subsequent years, and would include such assurances in plans' future bids and contracts. This policy applies to all Part D enrollees, not just those receiving a low-income subsidy.

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[27] CMS, *Transition Fact Sheet*, Mar. 31, 2006, at [http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1817.].

[28] CMS, *Transition Process Requirements for Part D Sponsors*, Apr. 2006, at [http://www.cms.hhs.gov/PrescriptionDrugCovcontra/Downloads/CY07TransitionGuidance.pdf].

[29] CMS, Centers for Beneficiary Choices, *Formulary Changes During the Plan Year*, memorandum to Part D sponsors, Apr. 26, 2006.

Long-Term Care Facility (LTC) Residents

Many dual eligibles are residents of long-term care (LTC) facilities. LTC residents are on average older and frailer than non-LTC residents; many also have cognitive impairments. These individuals do not access their prescriptions directly. In the past, the facility generally contracted with a single pharmacy to provide prescription supplies. The pharmacy dispensed drugs in special packaging to the facility; a nurse in the facility administered the drug to the patient. LTC facilities typically provided an open formulary to prescribing physicians that allowed immediate access to a variety of medications in different dosage forms and strengths.

Part D Requirements. The transition to the new Part D benefit resulted in significant changes. Long-term care residents now receive their drug coverage through Part D plans, not Medicaid. MMA required Part D plans to provide convenient access to prescription drugs for institutional residents. The regulations required Part D plans to offer standard contracting terms and conditions, including performance and service criteria, to all long-term care pharmacies in their service areas. Individuals in LTC facilities need to be sure that their plan contracts with a pharmacy serving the facility.

In the preamble to the final regulations, CMS outlined a process that was described as balancing the special needs of LTC enrollees with the need to inject competition into the long-term care pharmacy market. In March 2005, CMS issued a guidance document,[30] which outlined minimum criteria that plans must meet in four key areas: performance and service, convenient access, formulary, and exceptions and appeals.

The guidance document requires Part D plans to offer a contract to any pharmacy willing to participate in its LTC network so long as the pharmacy is capable of meeting minimum performance and service criteria (and relevant state laws) and other terms established by the plan for its network pharmacies. The performance and service criteria are based on widely used best practices in the market today. They include criteria relating to: comprehensive inventory and inventory capacity; requirements for a dispensing pharmacist including those related to drug utilization review; capacity to provide special packaging; provision of 24/7 on-call service with a qualified pharmacist; and delivery services, including emergency delivery services.[31]

The Part D plan must demonstrate that it has a network of participating pharmacies that provide convenient access for LTC residents that are Part D enrollees. It must also attest that it will assure that all future Part D enrollees who are institutionalized can routinely receive their benefits through the plan's network of pharmacies.

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[30] CMS, *Long-Term Care Guidance*, Mar. 16, 2005, at [http://www.com.hhs.gov/States/Downloads/Longtermcareguidance.pdf].

[31] CMS notes that these items would be legitimate costs to reflect in the dispensing fee. Specialized services provided in the administration of the drugs after they are dispensed and delivered from the LTC pharmacy are not covered under the Part D benefit.

Plans cannot have a different formulary for LTC residents (though some observers had recommended this). They are required to provide coverage for all medically necessary drugs. CMS notes that this can be achieved through inclusion of the drugs in the formulary, utilization management tools, or an exceptions process.

Finally, the exceptions and appeals process established by Part D sponsors is expected to consider the special circumstances of LTC enrollees. Sponsors are required to have procedures in place where there is a disparity between Part D requirements and Medicare conditions of participation for long-term care facilities.

On May 11, 2006, CMS issued a memo to state survey agency directors intended to clarify residents' rights regarding choice of a drug plan and pharmacy provider, and the facilities' responsibility to provide drugs to residents. The document noted that residents are guaranteed the right to choose a Part D plan, but do not have "unbridled freedom" to choose a pharmacy. The document cited a number of examples of situations that would frustrate a beneficiary's ability to receive drugs under his or her preferred Part D plan. CMS noted its expectation that nursing homes work with pharmacies to make sure that a resident's choices are honored. Specifically, CMS expects nursing homes to work with current pharmacies to assure that they recognize the plans chosen by the facility's beneficiaries, or alternatively to add pharmacies to achieve that objective. At its option, the facility could contract exclusively with another pharmacy that contracts more broadly with Part D plans. Since nursing homes are responsible for the safety and efficacy of medication delivery, they have the responsibility for selecting a pharmacy or pharmacies that are willing and able to accommodate the plans chosen by all the residents of the facility. Nursing homes may not coach, steer, or otherwise encourage a resident to select or change a plan. State surveyors are to continue to monitor compliance with regulations and guidelines.[32]

Implementation. MMA, together with the implementing regulations and guidance material, represented a major shift for LTC facilities and their dual eligible patients. While the initial stages of the transition apparently went somewhat more smoothly than some individuals had expected, several problem areas have been identified. (These are in addition to the enrollment issues and transition issues discussed above). Some identified by a March 2006 focus group of state Medicaid directors included the following: incorrect premium assessments were billed to dual eligibles; unit dose packaging was not provided for beneficiaries in residential care homes;[33] dispensing guidelines are significantly different from those applicable under Medicaid; and some long-term pharmacies had large Part D accounts receivable.[34]

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[32] CMS, Center for Medicaid and State Operations/Survey and Certification Group, *Nursing Homes and Medicare Part D*, memorandum to State Survey Agency Directors, May 11, 2006.

[33] Unit dose packaging systems are often used in nursing homes, group homes and similar facilities. Each dose is dispensed in individual packages and labeled with patient identifiers and administration instructions. This is intended to streamline procedures for staff and cut administration errors.

[34] Vernon Smith et al., *Observations on the Initial Implementation of the Medicare* (continued...)

Some observers feel that it would be helpful if nursing homes could help beneficiaries select a plan. However, this runs counter to CMS policy, which is based on the premise that if nursing homes are allowed to make recommendations, they could inappropriately influence plan selection.

Interaction With Other Programs

Patient Assistance Programs. A number of drug manufacturers have offered prescription drugs to low-income Medicare beneficiaries, as well as to other low-income persons with high drug costs. These pharmaceutical assistance programs (PAPs) are not connected with federal programs. PAPs operate in various ways. They may offer cash subsidies, free or reduced-priced drugs, or both. They may offer assistance directly to patients or replenish drugs furnished by pharmacies, clinics, and other entities.

Questions have been raised about the potential interaction between PAPs and Part D. In particular, observers questioned whether federal anti-kickback statutes would be implicated if PAPs continued to provide assistance to Medicare beneficiaries by subsidizing their Part D cost-sharing obligations. A special advisory bulletin issued by the Office of Inspector General on November 7, 2005, [35] stated that such arrangements would present heightened risk under the anti-kickback statute. This was based on the observation that subsidies would be prohibited by the statute because the manufacturer would be giving something of value (i.e., the cost-sharing subsidy) to beneficiaries to use its product. It further outlined several types of abuse that could occur, including steering beneficiaries to particular drugs, providing a financial advantage over competing drugs, reducing beneficiaries' incentives to locate and use less expensive drugs, and increasing costs to the program by shortening the time period before the beneficiary hit the catastrophic trigger.

The OIG did state, however, that there were other options drug manufacturers could consider. These included making cash donations to bona fide independent charity PAPs not affiliated with a manufacturer and operated without regard to donor interests. The OIG Bulletin also stated that PAPs entirely outside the Part D benefit could pose a reduced risk under the anti-kickback statute. In these cases, no claims could be made against the Part D plan for the drugs, and any cost-sharing could not count toward the beneficiaries TROOP. The bulletin stated that these programs would have to meet a number of conditions.

In response to the OIG Bulletin, many manufacturers announced that they would cease to provide PAP assistance to any Medicare beneficiary enrolled in Part D. In some cases, a beneficiary who did not enroll in Part D could continue to receive assistance through the PAP. However, there would be no guarantee that the PAP program would continue to offer the drugs indefinitely, nor would the individual have

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[34] (...continued)
Prescription Drug Program, Perspectives of State Medicaid Directors Through a Focus Group Discussion, Kaiser Family Foundation, May 2006.

[35] HHS, OIG, *Special Advisory Bulletin Provides Guidance On Patient Assistance Programs for Medicare Part D Enrollees*, Nov. 7, 2005.

help with the costs of drugs not covered under a PAP program. Further, a beneficiary delaying enrollment in Part D after the May 15, 2006 enrollment deadline would be subject to a delayed enrollment penalty.

The OIG Bulletin and the subsequent response by drug manufacturers raised the concern that some beneficiaries would be faced with significantly higher out-of-pocket costs. Members of the Senate Finance Committee, as well as other observers, asked the OIG to further clarify its position. In April 2006, the OIG issued an advisory opinion[36] that two PAPs proposed by one company would not subject it to sanctions. Under the arrangements, free drugs would not count toward TROOP. Once a beneficiary began receiving drugs through either of the PAPs, neither the Part D plan not the beneficiary would be charged for the drug for the remainder of the year. The company also entered into a data-sharing arrangement with CMS that would enable PAPs to notify Part D plans regarding beneficiary participation in the PAPs.

While the OIG Guidance applied to a specific approach offered by one company, it was seen as a roadmap for other companies. At the same time, the Senate Finance Committee was encouraging manufacturers to continue offering PAPs. Recent reports suggest that other companies are rethinking their position and will offer such programs.

State Pharmaceutical 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 persons enrolled in SPAPs are eligible for low-income subsidies under Part D. Other persons enrolled in state programs are not eligible for low-income subsidies because their incomes and/or assets exceed the requisite limits. However, SPAP payments made on their behalf to cover Part D cost-sharing charges will count toward the individual's true out-of-pocket (TROOP) costs trigger.[37]

Coordination With Part D — Initial Concerns. The enrollment of SPAP participants became a key issue for a number of states. 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. In its January 2005 regulations, 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

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[36] HHS, OIG, *OIG Advisory Opinion No. 06-03*, Apr. 18, 2006

[37] Prior to the implementation of Part D, several states had established pharmacy plus waiver programs. These programs provided drugs and primary care services under a Medicaid waiver. In the regulations, CMS stated that these programs could not qualify as SPAPs (in part because program expenditures were federally matched). Therefore, any pharmacy plus program expenditures could not count toward a beneficiary's TROOP. Currently, only Wisconsin has such a program for its Medicare population.

to counting TROOP. Supporters of this approach contend that the definition of SPAP, which includes the nondiscrimination provision, is important for MA organizations and PDP sponsors.

The inability to steer beneficiaries to a selected plan or plans effectively means that an SPAP can 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. States suggested that allowing auto-enrollment in preferred plans would allow them to leverage the potential of a large number of enrollees during the negotiation process. They stated that if they were not permitted to enroll individuals in preferred plans, they will be faced with potentially providing different wraparound benefits for different plans based on variations in formulary and cost-sharing structures.[38]

Coordination With Part D-CMS Policy. CMS established policies intended to balance the need to adhere to the nondiscrimination requirement with state concerns.

Coordination of Benefits. In July 2005, CMS issued its coordination of benefit guidance for Part D.[39] This guidance outlined the following four approaches that SPAPs could choose to provide their wraparound benefits: (1) paying premiums for basic and/or supplemental benefits; (2) wrapping around benefits at the point-of-sale; (3) contracting with Part D plans on a risk- or non-risk-based lump sum per capita method; or (4) some combination of these.

Under option 3, SPAPs would solicit lump sum per capita bids from Part D plans in exchange for the provision of wraparound benefits. The guidance document outlined steps SPAPs could adopt when paying lump sum per capita payments to Part D plans on a risk basis in order to be deemed nondiscriminatory with respect to the plan the individual was enrolled in. In brief, the process involves the following steps: (1) States wishing to adopt a lump sum per capita approach would define a uniform benefit package; (2) all Part D plans in the region would be invited by the state to submit a quote; (3) plans not wishing to participate would not be required to submit quotes and states would not be obligated to provide wraparound benefits to beneficiaries choosing such plans; (4) based on the submitted quotes, states would determine what it would pay based on either the actual quote of each plan or an amount equal to the 75th percentile of all quotes (with plans with higher quotes permitted to withdraw); (5) states would have to assure equal access to enrollment in and comparable information on all Part D plans participating in the chosen

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[38] The CMS approach runs counter to a key recommendation of the State Pharmaceutical Assistance Transition Commission which was established by MMA to provide advice on coordination and transition issues. The Commission's report, issued in December 2004, recommended that SPAPs should be allowed to endorse one or more preferred drug plans for their enrollees.

[39] CMS, *Part D Coordination of Benefits Guidance*, July 1, 2005, at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CobGuidance_07.01.05.pdf].

approach without any steering to individual plans; (6) states would be required to report the results of the bidding process; (7) Part D plans would be required to provide information identifying the SPAP as the co-provider of benefits; and (8) plans would be required to periodically provide claims data to the state. States selecting to pay non-risk-based lump sum per capita payments could do so as long as an equal subsidy amount was offered to each individual in each Part D plan; Part D plans would be required to provide claims data to SPAPs.

Authorized Representative.[40] CMS guidance also established a process for facilitated enrollment in cases where SPAPs are their members' legal representative under state law. SPAPs serving as authorized representatives could identify objective criteria (subject to CMS approval) that could narrow the range of options an SPAP would use to enroll a member in a plan. SPAPs with individualized data could use this to facilitate enrollment of certain groups of individuals into plans best suited to them in terms of pharmacy networks or specific drug needs.

State Actions. States have been revising their programs in light of the implementation of Part D. The National Conference of State Legislatures (NCSL) reports that states responded to the MMA changes in a variety of ways. In 2005 (before PDP plan design, formularies, or premium structures were known), many states enacted legislation to restructure their programs to wrap around Part D. Typically, this means that for persons eligible for both programs, SPAPS pay some portion of Part D premiums and/or cost-sharing and may cover some drugs excluded under the Part D benefit. At least five states established new SPAP programs, while another five are dropping their programs. Additional modifications are expected during 2006.[41]

Other Beneficiary Issues

Drugs Not Covered Under Part D. Several categories of drugs are specifically excluded by law from coverage under Part D. These include benzodiazepines (used to treat anxiety disorders) and barbiturates (used for treatment of some seizures), weight loss drugs, and over-the-counter medications. States will continue to be able to cover these drugs under Medicaid (and receive federal matching for these expenditures). However, some observers are concerned that beneficiaries may lose access to these drugs.

An HHS survey of 47 state Medicaid programs in December 2005 showed that 45 Medicaid programs would continue to cover non-prescription drugs, 46 states would cover benzodiazepines, 45 states would cover barbiturates, 35 would cover

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[40] [http://www.cms.hhs.gov/States/Downloads/QualifiedSPAPGuidelines.pdf].

[41] For an overview of current state programs see, NCSL, *National State Pharmaceutical Assistance Programs in 2006: Helping to Make Medicare Part D Easier and More Affordable*, at [http://www.ncsl.org/programs/health/SPAPCoordination.htm#Summary].

prescription vitamins and mineral products, and 32 states would cover drugs for symptomatic relief of cough and colds.[42]

Cost-Sharing for the Dual Eligible Population. Some non-institutionalized dual eligibles may see an increase in their cost-sharing charges. A 2004 comparison of Part D cost-sharing charges with those applicable under the low-income subsidy provisions showed that 11 states imposed no copayments on drugs, 13 states imposed charges that would always fall below Part D levels, five states had charges that were the same or higher than those under Part D, and 14 states had copayments that might be higher or lower than Part D levels, depending on the circumstances.[43]

An additional concern for some is that persons in assisted living facilities or under a home and community-based services waiver are not considered institutionalized for purposes of the cost-sharing waiver. It may be difficult for some of these individuals to afford the requisite copayments.

Value of Benefit over Time. The standard benefit described earlier, is the 2006 benefit. Under the 2006 benefit, the deductible is $250, the initial coverage limit is $2,250, the out-of-pocket amount is $3,600, and the total spending amount triggering catastrophic coverage is $5,100. (See **Table 1**.) All of these amounts are slated to increase each year. The Office of the Actuary of CMS has announced that in 2007, the deductible will be $265, the initial coverage limit will be $2,400, the out-of-pocket amount will be $3,850,[44] and the total spending amount triggering catastrophic coverage will be $5,451.25. By 2015, it estimates that the deductible will be $475, the initial coverage limit will be $4,290, the out-of-pocket amount will be $6,850, and the total spending amount triggering catastrophic coverage will be $8,282.50.

In large measure the low-income population in Group 1 will be protected from these cost-sharing increases, as well as any increases in the Part D premium (provided the individual elects a plan with a premium at or below the low-income benchmark). Dual eligible persons in Group 1 subject to the $1/$3 cost-sharing charges per prescription in 2006 will see these amounts increase each year by the percentage increase in the CPI (the 2007 amounts are $1/$3.10). Other persons subject to the $2/$5 cost-sharing charges per prescription in 2006 will see these amounts increase each year by the percentage increase in the per capita expenditures for Part D drugs. The 2007 amounts are $2.15/$5.35. Over time, these dollar amounts may increase at a faster rate than beneficiaries' incomes.

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[42] HHS, Office of the Inspector General, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, OEI-05-06-00090, Jan. 2006.

[43] The Kaiser Commission on Medicaid and the Uninsured, *Implications of the New Medicare Law for Dual Eligibles: 10 Key Questions and Answers*, The Henry J. Kaiser Family Foundation, Jan. 9, 2004.

[44] The Boards of Trustees of the Federal Hospital Insurance and the Federal Supplementary Insurance Trust Funds, *2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and the Federal Supplementary Insurance Trust Funds*, May 2006.

The annual updates in the standard benefit amounts will have larger implications for persons in Group 2. The $50 deductible applicable in 2006 will increase each year by the percentage increase in the per capita expenditures for Part D drugs; in 2007 it will be $53; by 2015 it will be an estimated $95. The 15% coinsurance applies to total drug spending between $50 and $5,100 in 2006. In 2015, it will apply to drug spending between approximately $95 and $8,282.50.

Persons in Group 2 are also subject to a sliding scale premium ranging from zero at 135% of poverty to 100% at 150% of poverty. Actual premium amounts are expected to go up each year. CMS actuaries estimate that the average Part D premium amount for all beneficiaries will rise from about $32.20 in 2006 to $59.88 in 2015. Individuals in Group 2 will be liable for some portion of the increase.

Some persons in both groups may receive assistance with Part D cost-sharing through their state pharmaceutical assistance programs.

State Issues

State Contributions Toward Part D Costs

"Clawback Requirement". Effective January 1, 2006, states are no longer providing coverage for Part D drugs for their dual eligible population. They could be expected to see a reduction in their Medicaid spending as a result of this transfer. However, the law contains 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. Initially, states would assume 90% of these costs; over the next nine years the states' contribution would gradually decline to 75%.[45]

Below is the formula for the clawback:

[45] See also CRS Report RS21837, *Implications of the Medicare Prescription Drug Benefit for Dual Eligibles and State Medicaid Programs*, by Karen Tritz.

State Payments: "Clawback"

States are required to pay the Secretary each month an amount equal to the *product* of:

A. 1. Projected per capita monthly drug payment equal to the *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

Current state matching rate.

A. 2. Increased for each year by the applicable growth factor.

For 2004, 2005, and 2006, the national health expenditure estimates of percentage increases in drug spending, in subsequent years the per capita percentage increase in Part D expenditures.

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

C. The factor for the month:

2006 — 90%
2007 — 88 1/3%
2008 — 86 2/3%
2009 — 85%
2010 — 83 1/3%
2011 — 81 2/3%
2012 — 80%
2013 — 78 1/3%
2014 — 76 2/3%
2015 and later — 75%.

The final regulations provided an illustrative calculation of the "clawback" and provided a data source for each item. Generally, state Medicaid Statistical Information System (MSIS) and information reported on the form CMS-64 are used.

In October 2005, each state Medicaid Director was notified by CMS of the per capita monthly payment amount that would be assessed for each full benefit dual eligible enrolled in the state's Medicaid program in 2006. These figures were revised downward in February 2006, based on revised estimates of the national health expenditures growth rate.

Clawback Issues. The MMA has been described as providing states some relief for expenditures they would otherwise incur for their dual eligible populations. However, with both the implementation of the "clawback provision" and the additional administrative responsibilities, many observers have suggested that the states will actually spend more than they would in the absence of MMA.[46] Others,

[46] Robert Pear, "Cost-Cutting Medicare Law is a Money Loser for States," *New York Times*, Mar. 25, 2005.

however, contend that the states will see savings, particularly over time, as their share of expenditures (as measured under the clawback formula) declines.

One of the key components of the clawback formula is actual drug expenditures in 2003. Many contend that the data base for 2003 is flawed. Further, states point out that while they have been implementing significant cost control mechanisms, any measures implemented since 2003 are not factored into the calculation. An additional concern is that clawback payments are required monthly, rather than quarterly which is the case for other Medicaid reporting activities.

On March 3, 2006, five states filed suit with the U.S. Supreme Court. The suit alleges that the clawback provision is unconstitutional because it requires states to pay for a federal program over which they have no control. The states took the case to the Supreme Court, arguing that first, the claims are of great constitutional importance because they are aimed at preserving the states' rights as independent sovereigns, and second, that there was no adequate alternative forum for a timely and final resolution of the states' claims. The states sought a preliminary injunction to block the clawback payments. On May 15, 2006, the Department of Justice filed a brief for the Secretary of the Department of Health and Human Services, stating that the motion for leave to file a bill of complaint and the motion for a preliminary injunction should be denied. As of this writing, the Court has not acted.

Other Budget Issues

The clawback requirement has significant implications for state budgets. Other aspects of MMA will also affect state spending. For example, outreach for the drug benefit is expected to result in a "woodwork" effect, with an expansion in the population enrolling in Medicaid and Medicaid savings programs.

Additionally, new enrollees who are full dual eligibles will be included in the formula for the calculation of the clawback obligation. Some persons have raised concerns about the longer term implications for state programs facing fiscal challenges. In an effort to control costs, states might limit the number of dual eligibles by cutting back or limiting the number or types of optional eligibility groups, limiting benefits, or cutting outreach activities.[47]

Other Issues

Impact on Medicaid's Drug Program. The transition of drug coverage for the dual eligibles to Part D was expected to result in a drop of about 50% in Medicaid drug spending. This represents a loss in market share for Medicaid. As a result, some persons have questioned whether states will have the same leverage to negotiate lower prices for the remainder of their Medicaid population receiving drug benefits.

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[47] National Health Policy Forum, *Implementing the New Medicare Drug Benefit: Challenges and Opportunities for States*, NHPF Meeting Report, Aug. 31, 2004.

Interaction Between Part D and Medicaid. States are concerned about their ability to track drug utilization for the dually eligible population. Pharmacy data are one of fastest ways to pick up clinical problems, as well as potential fraud.

Another concern is that state Medicaid programs will not have control over the drugs used by the dual eligible population. They will no longer be able to achieve savings through their own cost control mechanisms. They will, however, be responsible, through Medicaid, for any increases in other medical spending resulting from inappropriate drug use.

Estimated Impact

CBO and CMS have estimated the impact of the Part D provisions.

CBO Cost Estimates

In March 2006, CBO provided updated estimates of the drug benefit, including its estimates relating to low-income participation. It estimated Part D Medicare spending at $29.1 billion in FY2006, $57.8 billion in FY2007, and rising to $116.5 billion in FY2011; and that spending under the low-income subsidy provisions would total $9.9 billion in FY2006, $14.6 billion in FY2007, and rise to $25.7 billion in FY2011. It estimated that there would be 8.7 million low-income subsidy enrollees in FY2006, 9.5 million in FY2007, and rise to 10.8 million by FY2011. It also estimated that payments by the states under the "clawback" provision would total $3.8 billion in FY2006, $7.0 billion in FY2007, $7.7 billion in FY2008, $8.5 billion in FY2009, $9.2 billion in FY2010, and $10.0 billion in FY2011.[48]

CMS Enrollment Estimates

Enrollment. When CMS published its final Part D regulations in January 2005, it estimated that 14.4 million beneficiaries would be eligible for the low-income subsidy in 2006; of these, it expected 10.9 million persons would actually receive assistance.[49] These estimates were subsequently revised.[50]

On May 10, 2006, CMS estimated that as of May 7, 2006, 13.2 million persons were eligible for the low-income subsidy. Of these, 9.0 million persons were getting subsidy benefits, and 1.0 million had drug coverage through other sources; the remaining 3.2 million persons remained subsidy-eligible but had not signed up. Dual eligibles represented approximately 6.4 million of the 9.0 million subsidy

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[48] CBO, *Fact Sheet for CBO's March 2006 Baseline: Medicare*, Mar. 2006.

[49] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Medicare Program; Medicare Prescription Drug Benefit;* Final rule, 70 *Federal Register* 4460, Jan. 25, 2005.

[50] When CMS issued its final regulations in January 2005, it provided cost estimates for spending on various categories of persons eligible for the low income subsidy. CMS has not published updated estimates.

beneficiaries. Of these, 5.9 million were automatically enrolled in stand-alone PDPs, with the remaining 0.5 million receiving coverage through MA-PD plans. Of the remaining 2.6 million subsidy-eligible enrollees, 2.1 million were enrolled in stand-alone PDPs, and 0.5 million were enrolled in MA-PD plans. Further, 7.3 million of 9.0 million subsidy-eligible enrollees had been deemed eligible for benefits, with the remaining 1.7 million determined eligible by SSA.

These numbers do not reflect persons signing up during the last week of the initial general enrollment period. Further, the May 15, 2006 deadline and the late enrollment penalty do not apply for persons subsequently determined eligible for a low-income subsidy. Therefore, the number of covered persons can be expected to increase over the coming months.

Concluding Observations

MMA established a new prescription drug benefit for the Medicare population. MMA represented a major change for the Medicare program. For the first time, specified program benefits, namely coverage for prescription drugs, vary based an individual's income level. Further, beneficiaries wishing to access the drug benefit are only able to do so through enrollment in a private stand-alone drug plan or a managed care plan with a drug benefit.

Implementation of the new program, particularly for the low-income population, proved challenging. While some of the initial problems have been somewhat mitigated, many administrative issues remain. Further, not all of the population potentially eligible for low-income subsidies has enrolled in the program. It is hoped that the waiver of both the enrollment deadline and the enrollment penalty for this population in 2006 will encourage more persons to enroll during the remainder of the year.

It should be noted that some low-income enrollees may face unanticipated changes in plan enrollment in 2007. One reason is because there is likely to be changes in plan offerings. PDP sponsors are likely to consolidate plans, thereby resulting in a smaller number of plans overall. A second reason is that some plans with 2006 premiums at or below the low-income benchmark may have 2007 premiums above the benchmark. In such cases, beneficiaries will need to change plans if they are to continue to have the same premium subsidy in 2007 (100% for those under 135% of poverty, and a sliding scale for those over 100% and up to 150% of poverty). CMS has stated that if the PDP sponsor offers another plan in the same area with a premium at or below the subsidy amount, the PDP sponsor will reassign full benefit dual eligibles to that plan. If the PDP sponsor does not offer such a plan, CMS will randomly auto-assign these dual eligibles to another plan in the service area. As of this writing, CMS has not stated whether this approach will be applied to other low-income individuals.

It is expected that the Congress will continue to monitor program implementation, particularly as it affects the low-income population.