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Medicare Prescription Drug Benefit: Low-Income Provisions

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Jennifer O'Sullivan
Specialist in Social Legislation
Domestic Social Policy Division

Congressional Research Service

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Medicare Prescription Drug Benefit: Low-Income Provisions

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 (and assets below specified levels) 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, proved challenging. The main concern now is the fact that, despite extensive federal, state, and local outreach efforts, not all persons potentially eligible for a low-income subsidy (LIS) have enrolled in the program. As of January 2007, the Centers for Medicare and Medicaid Services (CMS) estimated that 3.3 million persons eligible for LIS had neither signed up for Part D nor had coverage through another source. It is not immediately clear why some individuals have failed to enroll, though several factors, including a lack of program awareness, the nature of the application process itself, and the assets limits presumably each play a role. It is hoped that the continued waiver of both the enrollment deadline and the delayed enrollment penalty for the low-income population in 2007 will encourage more persons to enroll during the remainder of the year.

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.

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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, 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.

The main concern now is the fact that, despite extensive outreach efforts, not all persons potentially eligible for a low-income subsidy (LIS) have enrolled in the program. As of January 2007, CMS estimates that 3.3 million persons eligible for LIS are not enrolled. It is not immediately clear why some individuals have failed to enroll, though several factors, including lack of program awareness, the nature of the application process itself, and the assets limits presumably each play a role. It is hoped that the continued waiver of both the enrollment deadline and the delayed enrollment penalty for the low-income population in 2007 will encourage more persons to enroll during the remainder of the year.

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. This is followed by a review of enrollment procedures and polices applicable for this population. 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. In January 2007, CMS estimated that

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[3] Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), *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.

the average monthly plan premium for all plans (both PDPs and MA-PDs) at $22;[5] this represents about 25% of the total cost of the benefit.

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 at least actuarially equivalent benefits (i.e., having at least equivalent dollar value). In both cases, access must be provided to negotiated prices for drugs.

For 2007, the "standard prescription drug coverage" is defined as follows:

- $265 deductible paid by the beneficiary;
- 75% of costs paid by the program and 25% of costs paid by the beneficiary up to the initial coverage limit ($2,400, accounting for $798.75 in total out-of pocket costs and $2,400 in total spending);
- 100% of costs paid by beneficiary for drug spending falling in the coverage gap between $2,400 and $5,451.25 ($3,051.25, accounting for total beneficiary out-of-pocket spending of $3,850); and
- all costs paid by program over $5,451.25 in total spending (the "catastrophic" trigger) except for nominal beneficiary cost-sharing defined as the greater of: (1) a copayment of $2.15 for generic drug or preferred multiple source drug and $5.35 for other drugs; or (2) 5% coinsurance.

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

MMA specifies that beneficiaries must incur a certain level of out-of-pocket costs ($3,850 in 2007) 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.

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[5] HHS, CMS. *Medicare Drug Plans Strong and Growing*, Press Release, January 30, 2007. (It should be noted that inclusion of MA-PD plans lowers the overall average. The Kaiser Family Foundation reports that the average 2007 premium for PDPs nationwide is $36.66 [http://www.kff.org/medicare/healthplantracker/topicresults.jsp?i=33&rt=2].

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.[6]

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 ($13,783 for an individual and $18,481 for a couple in 2007); and (3) have resources in 2007 below $6,120 for an individual and $9,190 for a couple (increased each year by the percentage increase in the consumer price index, or CPI). The 2007 resource limits are generally publicized as $7,620 and $12,190 because $1,500 per person is excluded for burial expenses.

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[6] It should be noted that the law permits plans to offer the general population either the defined standard benefit or "actuarially equivalent" benefits. Most plans offered in 2007 are not for defined standard benefits, but rather for one of three alternatives. Some plans provide an actuarially equivalent standard benefit; under this benefit, plans impose tiered cost-sharing, that is, cost-sharing percentages that vary by whether the drug is generic or brand or preferred or not preferred. Some plans offer a basic alternative that can include both revised cost-sharing and a reduction in the deductible. Some plans are defined as enhanced alternative plans; these are plans that offer coverage whose value exceeds that of standard coverage; these plans typically offer some coverage in the doughnut hole. 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.

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 (QMBs)[7], (2) specified low-income Medicare beneficiaries (SLMBs)[8], and (3) qualifying individuals (QI-1s).[9,10]

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 ($15, 315 for an individual and $20, 535 for a couple in 2007); and (3) have resources in 2007 below $10,210 for an individual and $20,410 for a couple (increased in future years by the percentage increase in the

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[7] QMBs are aged or disabled persons with incomes at or below the federal poverty level. In 2007, the monthly level is $871 for an individual and $1,161 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.

[8] SLMBs meet the QMB criteria, except that their income is between 100% and 120% of the federal poverty level. In 2007, the monthly income limits are $1,041 for an individual and $1,389 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.

[9] 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 2007, the monthly income limit for QI-1 for an individual is $1,169 and for a couple $1,561. Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium.

[10] 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.

CPI). The publicized resource limits of $11,710 and $23, 410 include a $1,500 per person burial allowance.

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

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

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

Low-Income Subsidy (LIS) 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 $3.10 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 $2.15 for a generic drug or preferred multiple source drug and $5.35 for any other drug.[11] (See **Table 1**.)

Beneficiaries in Group 2 have a $53 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 $2.15 for a generic drug prescription or preferred multiple source drug prescription and $5.35 for any other drug prescription. (See **Table 1**.)

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

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[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, 2007

(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-$265	0	$265	$265	0	$212	$53
$265.01-$2,400	75%	25%	100% less enrollee cost-sharing	Institutionalized duals: $0 Duals under 100% of poverty: $1/$3.10[b] Others: $2.15/$5.35[c]	85%	15%
$2,400.01 - $5,451.25	0	100%	100% less enrollee cost-sharing	Institutionalized duals: $0 Duals under 100% of poverty: $1/$3.10[b] Others: $2.15/$5.35[c]	85%	15%
$5,451.26 and over	95%[a]	5%	100%	0	100% less enrollee cost-sharing	$2.15/$5.35[c]

Source: CMS, Office of the Actuary: *Medicare Part D Benefit Parameters for Standard Benefit: Annual Adjustments for 2007*, Apr. 5, 2006.

a. Assumes enrollee has met true out-of-pocket (TROOP) threshold of $3,850.
b. $1 per prescription for generic or preferred drugs that are multiple source drugs; $3.10 per prescription for other drugs.
c. $2.15 per prescription for generic or preferred drugs that are multiple source drugs; $5.35 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.

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. Special procedures have been established to make the process easier. The procedures are different for different categories of low-income enrollees.

General Requirements

In general, persons first eligible for Medicare on or before January 31, 2006, had to enroll with a Part D plan by the close of the initial enrollment period on May 15, 2006. Persons first eligible in February 2006 had until the end of May 2006 to enroll.

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

Persons newly eligible for Medicare at a later date have an initial seven-month enrollment period beginning three months before the month of Medicare eligibility and ending seven months later.

Failure to enroll at the first opportunity generally means that an individual can not enroll until the next annual open enrollment period (November 15-December 31), with coverage beginning the following January. Further, these persons are subject to a late enrollment penalty if they go for more than 63 days without creditable drug coverage (namely, coverage at least as good as standard Part D coverage).

However, the closing dates and application of the late enrollment penalty have been waived, for both 2006 and 2007, for persons deemed eligible for a low-income subsidy.

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, SLMBs, 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. Eligibility was redetermined in 2006 for 2007; persons were notified in September 2006 if their subsidy status was changing.

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 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 can no longer receive Medicaid coverage for drugs covered under Part D. The law required automatic enrollment for dual eligibles who failed to enroll in a PDP or MA-PDP plan. Individuals were enrolled with the plan in the region that had a premium not exceeding the premium subsidy amount. If more than one such plan was available, enrollment among these plans was made on a random basis. Individuals were to be informed in advance of the selected plan. Nothing prevented an individual from declining such enrollment or disenrolling from the plan in which he or she was enrolled and enrolling in a different plan. Further, dual eligibles could 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.

The auto-enrollment process is ongoing for persons newly establishing eligibility. In July 2006, CMS announced that it was implementing a process for auto-enrolling prospective full benefit dual eligibles. CMS requested assistance from the states in identifying persons who are about to become Medicare eligible either because they will shortly turn 65 or they are disabled persons reaching the end of the two-year waiting period for Medicare.

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 applied for and were approved for low-income

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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.

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.

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.

Special Provisions for 2006 and 2007. In 2006, CMS established a special enrollment period for persons eligible for a low-income subsidy.[14,15] Specifically, *persons deemed eligible for a low-income subsidy after the close of the initial enrollment period on May 15, 2006, could still enroll in a Part D plan in 2006. These late enrollees were not subject to the late enrollment penalty otherwise applicable to persons who missed the 2006 enrollment deadline*. This policy has been extended for an additional year through 2007.[16]

2007 Enrollment Changes for Persons Enrolled in LIS in 2006

Policies Directed at Reducing the Number of Persons Switching Plans. CMS established two policies for 2007 that have the effect of reducing the number of persons who would be forced to switch plans from 2006 to 2007 because the plan's 2007 premium exceeds the low-income premium subsidy amount.[17]

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

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

[16] CMS. *No Medicare Part D Late Fee for Low-Income Enrollees, CMS Says*. Press Release, Jan. 9, 2007.

[17] CMS, *Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries*, memo to plan sponsors, June 8, 2006.

Calculation of Benchmark Premium. The law provides that the low-income premium subsidy amount in a region is equal to the low-income benchmark amount for the region, but in no case less than the lowest beneficiary premium for a PDP in the area. The low-income benchmark is defined as the weighted average premium, with the weight based on plan enrollment. For 2006, the program's first year, all PDPs were assigned an equal weight. Beginning in 2007, the bid amounts were to be weighted by plan enrollment in 2006. However, since many beneficiaries selected low-cost plans, using a weighted average would have the effect of reducing the regional low-income benchmark premium amounts. Instead, CMS decided to transition to the weighting methodology. For 2007, it used the same methodology used for 2006.[18,19] In future years, it will move toward actual enrollment weighting.

"De Minimus" Policy. In addition, CMS established a "de minimus" policy for 2007. This is intended to reduce the number of persons in Group 1 who would otherwise have been reassigned because the 2007 premium exceeds the full low-income subsidy amount. No reassignment was made if the premium is below a "de minimus" amount (i.e., the full subsidy amount in the region plus $2). These beneficiaries pay no premiums even if the plan premium is in the "de minimus" range. However, the "de minimus" policy does not apply to new auto or facilitated enrollments in 2007; PDPs that qualify for the "de minimus" policy will not receive new auto/facilitated enrollments because their premiums are above the 2007 LIS benchmark.

Persons qualifying for partial premium subsidies do not qualify for the "de minimus" policy; they are required to pay in full the difference between the subsidy amount and the plan premium.[20]

Events Affecting a Change in LIS Status. There are, however, other circumstances under which a low-income subsidy-eligible person experienced a change from 2006 to 2007. These include cases in which an individual 1) was enrolled in a plan in 2006 whose 2007 premium will no longer fall below full LIS coverage; 2) was enrolled in a plan that terminated its participation in Part D; 3) lost automatic eligibility for the low-income subsidy in 2007; or 4) fell into a different subsidy category.

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[18] CMS, *Release of the 2007 Part D National Average Monthly Bid Amount, the Medicare Part D Base Beneficiary Premium, the Part D Regional Low-Income Premium Subsidy Amounts, and the Medicare Advantage Regional Benchmarks*, letter to plan sponsors, Aug. 15, 2006 [http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/ptcd2007_20060815.pdf].

[19] CMS states that the 2007 low-income benchmark premium in the 34 PDP regions ranges from $20.56 in Nevada to $33.56 in Alaska [http://www.cms.hhs.gov/medicare advtgspecratestats/Downloads/PartD2007.zip].

[20] CMS, *Clarification on De Minimis Premium Policy for Low-Income Subsidy Eligible Beneficiaries*, letter to plan sponsors, October 27, 2006 [http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoDeMinimisClarification_10.27.06.pdf].

Individuals Enrolled in Plans that no Longer Have Premiums Below full LIS Coverage or in Plans that Terminate . CMS established a process for reassigning these beneficiaries to a different Part D plan. Beneficiaries to be reassigned must meet all of the following criteria:

- They were deemed eligible for a subsidy in 2006 because they were dual eligibles, participants in a Medicare Savings Program, SSI recipients, or because they applied and were found eligible for the subsidy;
- they continue to be eligible for a subsidy in 2007;
- they were originally auto-enrolled or had their enrollment facilitated into a PDP;
- they did not elect to enroll in a different plan; and
- their 2006 plan has a 2007 premium that is above the "de minimus" amount (which is the subsidy amount in the region plus $2) or is terminating at the end of 2006.

Beneficiaries meeting all of these criteria were reassigned to a different PDP in the region as follows. The beneficiaries were assigned to another plan in the same region offered by the same PDP sponsor, if the sponsor had a plan with a premium at or below the full subsidy level. (If there was more than one such plan, CMS randomly assigned beneficiaries among these plans.) If no such plan existed, CMS randomly assigned beneficiaries among PDP sponsors with at least one plan with a premium at or below the benchmark. CMS notified beneficiaries of their plan assignment in November 2006. However, beneficiaries could voluntarily elect to stay in their same plan (if it was still offered) or select a different plan from the one assigned by CMS.

Beneficiaries who changed plans in 2006 after they were either auto-assigned to a plan or had their enrollment facilitated into a plan did not have their selection changed by CMS. The beneficiary is free to change his or her selection.

Individuals Losing Automatic Eligibility for Low-Income Subsidy. Persons automatically qualifying for a low-income subsidy are dual eligibles, persons enrolled in Medicare Savings programs, and SSI recipients. At the end of September 2006, CMS began sending letters to those beneficiaries losing their automatic eligibility for a low-income subsidy in 2007 because they no longer fell into one of these categories. At the same time, these beneficiaries were told they still might qualify for assistance and were encouraged to file a low-income subsidy application with SSA. The application and a postage-paid envelope were enclosed with each notice.

Redeterminations are also made for other low-income persons. The law requires individuals who applied for and qualified for LIS to re-establish their eligibility each year with the agency that made the initial determination (SSA or state Medicaid office). Most determinations have been made by SSA. In August 2006, SSA sent a letter to persons who had applied directly to SSA and qualified for a low-income subsidy before May 2006. If an individual's income or resources changed, they had to complete a new redetermination form for 2007. People who applied to SSA after April 2006 will have a redetermination made later this year. Individuals who applied

through state Medicaid offices have redeterminations made according to individual state rules.

Individuals Falling Into a Different Subsidy Category. Beneficiaries whose subsidy category was changing in 2007 received a separate notice in October 2006 informing them of this change.

Special Enrollment Period. CMS is providing a one-time special enrollment period from January 1, 2007, to March 31, 2007, to allow any individual who no longer qualifies for a low-income subsidy to make a one-time part D election. Additionally, CMS also stated that plan sponsors may choose to offer up to a three-month grace period for the collection of premiums and cost-sharing charges for those persons who can demonstrate that they have applied for a low-income subsidy. Sponsors may recoup any uncollected amounts if, after this period, the individual is not eligible for the subsidy.

Eligibility and Enrollment Issues

Initial Start-Up; Dual Eligibles[21]

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.

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 noted that many individuals might not be aware of the transition and/or might not know which plan they were enrolled in. In response to these concerns, CMS established a backup process for any dual eligible arriving at a pharmacy without necessary documentation.

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 electronic eligibility inquiry (E1) system. Subsequently, CMS released additional guidance for drug plans and pharmacists, and dedicated additional resources to try and resolve these issues. While the initial transition issues have been addressed, concerns continue to be raised regarding the accuracy and timeliness of data used to make eligibility determinations.

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[21] 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.

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;[22] with some states receiving extensions to March 31, 2006; CMS extended 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.[23] However, a letter from the National Governor's Association in February 2007 indicated a few states had yet to be reimbursed fully.[24]

Enrollment for Other Low-Income Persons

CMS estimates that as of January 2007, there are approximately 3.3 million persons potentially eligible for a low-income subsidy who are neither enrolled in Part D nor recorded as having other creditable coverage.

A number of efforts have been made to contact potential LIS individuals. These have included a number of outreach activities by SSA, including educational activities and targeted mailings and followup phone calls to persons identified as being possibly eligible for assistance. Additionally, a variety state and local agencies and beneficiary advocacy groups have conducted extensive educational activities. Despite these efforts, some potential eligibles have not enrolled. Possible reasons cited for non-enrollment include persons either not being aware of the benefit, not understanding the application process, or thinking they will not qualify.

The fact that an individual has applied for a LIS does not automatically mean that the individual is eligible. SSA reported that as of mid-January 2007, it had received applications from 6.1 million beneficiaries; of these, almost 1 million were unnecessary because either the applicants were automatically eligible or because they had filed more than one application. The agency had made more than 5.9 million determinations; more than 2.3 million of these were deemed to be subsidy-eligible.[25]

Many observers contend that the relatively low percentage of eligibles reflects the program's assets limitations. 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

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[22] CMS used Section 402 demonstration authority; this is Section 402 of the Social Security Act of 1967 (P.L. 90-248), as amended.

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

[24] National Governors Association, letter from Governors Jon S. Corzine and Jim Douglas, to Michael O. Leavitt, Secretary of HHS, Feb. 12, 2007.

[25] U.S. Congress, Senate, Special Committee on Aging, Statement of Beatrice Disman, Chairman Medicare Planning and Implementation Task Force, Social Security Administration, Jan. 31, 2007.

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.[26] 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.

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

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[26] 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*, April 2005.

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 Beneficiary Issues

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 for 2006.[27] Of the top 200 drugs most commonly used by the dual eligible population in 2005, 178 were eligible for PDP coverage and 22 were excluded (see below). The OIG noted that this population group was being assigned to 409 PDPs that used 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 had 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 subsequently switched plan enrollment.

A similar analysis of 2007 Part D offerings for the LIS population is not currently available.

Transition Policies. CMS has established transition policies intended to assure that new plan enrollees do not abruptly lose coverage for their drugs. In April 2006, CMS announced the transition process requirements for 2007, which include the minimum standards plans are required to meet. Specifically, plans are required to provide a temporary supply fill anytime within the first 90 days of a beneficiary's enrollment in a plan. The supply must be for 30 days (unless the prescription is written for less than 30 days) for any nonformulary drug. The requirement also applies to drugs that are on a plan's formulary, but that require prior authorization or step therapy. In long-term care facilities, the transition policy provides for a 31-day fill, with multiple fills as necessary, during the first 90 days of a beneficiary's enrollment in a plan. After the 90-day period, the plan must provide a 31-day emergency supply while an exception is being processed. (CMS has specified 31 days because many long-term care pharmacies dispense medications in 31-day increments.)[28]

In November 2006, CMS sent a letter to Part D plan sponsors reminding them of the transition policies. The letter noted that the purpose of the process was not just to provide a temporary fill of non-formulary drugs, but rather to provide enrollees

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[27] 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.

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

with sufficient time to work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request an exception based on grounds of medical necessity.[29]

Formulary Changes. Certain policies govern formulary changes.

Mid-Year 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.[30] 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.

Year-to-Year Changes. As noted, plans can change their formularies at the beginning of the year. This will affect those beneficiaries whose drugs are either no longer covered by the plan or covered under different conditions. CMS, in its November transition letter to plan sponsors, outlined the transition policies that must apply in such cases. Plans could either apply the transition rules applied to new enrollees (as outlined above), or they could effectuate the transition prior to January 1, 2007, by transitioning an enrollee to a therapeutically appropriate formulary alternative or processing an exceptions request by that date.

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[29] CMS, *Reminder of Part D Transition Policy and Expectations for the Coming Contract Year*, letter to Part D plan sponsors, Nov. 1, 2006.

[30] 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,[31] 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.[32]

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

[32] 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.[33]

Impact on Beneficiaries. Many observers have stated that nursing homes and other caregivers should be allowed to 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.

The Long Term Care Pharmacy Alliance (LTCPA) recently issued a report highlighting what it sees as the implications of this policy for beneficiaries.[34] Specifically, it stated that nursing home residents have a poor chance of being enrolled in the Part D drug plan that best covers their medications. It noted that many individuals had been randomly assigned to plans under the autoenrollment process. There are wide variations among these plans. LTCPA's included a state-by-state analysis of plans, with premiums below the low-income benchmark, based on

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[33] 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 [http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06-16.pdf].

[34] Long Term Care Pharmacy Alliance. *State-by-State Formulary Variability in Medicare Prescription Drug Plans for Auto-Assigned Long-Term Care Residents*, February 2007 [http://www.ltcpa.org/pdf/LTCPA_2007_Regional_PDP.pdf].

coverage of 10 drugs commonly prescribed to long-term care residents. It cited New York where 80,000 low-income nursing home residents could select among 13 plans. Three of the plans covered all drugs, with restrictions (such as requiring prior authorization or step therapy) for only one drug. The other 10 plans did not cover all of the drugs; 2 of these plans excluded 4 drugs and placed restrictions on an additional 4 drugs.

The LTCPA stated that since many residents could change enrollment monthly, they could immediately switch to a better plan at no cost if they were allowed to receive help from their caregivers. Few frail elderly beneficiaries currently change plan enrollment. The LTCPA stated that because nursing homes residents are typically very elderly and in poor physical and mental health, most are unable to evaluate, choose and enroll in a plan on their own.

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).[35] 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 prescription vitamins and mineral products, and 32 states would cover drugs for symptomatic relief of cough and colds.[36]

Cost-Sharing for the Dual Eligible Population. Some non-institutionalized dual eligibles may have seen an increase in their cost-sharing charges when they transitioned from Medicaid to Part D. 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.[37]

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[35] P.L.100-91, enacted October 20, 2005, prohibits Medicaid coverage of erectile dysfunction drugs, effective Jan. 1, 2006, and Part D coverage of such drugs, effective Jan. 1, 2007.

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

[37] 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.

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 2007 benefit. Under the 2007 benefit, the deductible is $265, the initial coverage limit is $2,400, the out-of-pocket amount is $3,850, and the total spending amount triggering catastrophic coverage is $5,451.25. (See **Table 1**.) These amounts are more than 6% greater than the 2006 levels. All of these amounts are slated to increase each year. In May 2006, the Office of the Actuary of CMS announced that by 2015, 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.[38]

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/$3.10 cost-sharing charges per prescription in 2007 will see these amounts increase each year by the percentage increase in the CPI (the 2006 amounts were $1/$3.00). Other persons subject to the $2.15/$5.35 cost-sharing charges per prescription in 2007 will see these amounts increase each year by the percentage increase in the per capita expenditures for Part D drugs. (The 2006 amounts were $2.00/$5.00.) Over time, these dollar amounts may increase at a faster rate than beneficiaries' incomes.

The annual updates in the standard benefit amounts will have larger implications for persons in Group 2. The $53 deductible applicable in 2007 will increase each year by the percentage increase in the per capita expenditures for Part D drugs; by 2015 it will be an estimated $95. The 15% coinsurance applies to total drug spending between $53 and $5,451.25 in 2007. In 2015, it will apply to drug spending between approximately $95 and $8,282.50.[39]

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; though estimates that the year-to-year increases will be less than originally anticipated. 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.

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[38] 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.

[39] Ibid.

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, [40] 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 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,

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

asked the OIG to further clarify its position. In April 2006, the OIG issued an advisory opinion[41] 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. Subsequently, The OIG issued additional guidance documents to other manufacturers interested in offering PAPs.

Further clarification has been provided by CMS. It has specified that programs operating outside of the Part D benefit are not precluded from assessing nominal beneficiary copayments. These nominal copayments may count toward a beneficiary's TROOP, provided the beneficiary takes the responsibility for submitting the appropriate documentation to his or her plan.[42]

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.[43]

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 to counting TROOP. Supporters of this approach contended that the definition of

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

[42] 1)CMS, Medicare Prescription Drug Benefits Manual [http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/PDMChapt14COB.pdf].

[43] 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.

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 meant that an SPAP could not auto-enroll its participants in preferred Part D plans. This proved to be a concern for some states who argued they should be able to enroll their beneficiaries in preferred plans if they gave individuals the option to switch to other plans if they wanted to. 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 would be faced with potentially providing different wraparound benefits for different plans based on variations in formulary and cost-sharing structures.[44]

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. This guidance, which was subsequently incorporated into the Prescription Drug Benefit Manual,[45] 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 approach without any steering to individual plans; (6) states would be required to

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[44] The CMS approach ran 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.

[45] CMS, Medicare Prescription Drug Benefit Manual, Chapter 14, Coordination of Benefits, [http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/PDMChapt14COB.pdf].

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.[46] 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 revised 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. Some states modified existing programs to coordinate with Part D, established new state programs, or in the case of five states, dropped existing programs. The majority of current programs provide wrap around benefits.. 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. As of February 2007, NCSL reports that over 1.5 million persons in 20 states receive some subsidy assistance under one of these programs.[47]

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%.

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

[47] NCSL, State Pharmaceutical Assistance Programs in 2006-07: Helping to Make Medicare Part D Easier and More Affordable, updated February 2, 2007. [http://www.ncsl.org/programs/health/SPAPCoordination.htm].

Below is the formula for the clawback:

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.

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 suggested that the states would actually spend more than they would in the absence of MMA.[48] Others, however, contended that the states would see savings, particularly over time, as their share of expenditures (as measured under the clawback formula) declined.

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

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 had implementing significant cost control mechanisms, any measures implemented since 2003 were not factored into the calculation.

On February 12, 2007, the National Governors' Association sent a letter to HHS requesting that the states's 2007 contribution be adjusted to reflect actual program spending. The Association contends that CMS should compare the rates paid to plans in 2007 versus 2006, rather than using the general health care index to make the calculation. The Governors noted that Part D is operating below budget and therefore, states should share in the savings.[49]

Other Budget Issues

The clawback requirement has significant implications for state budgets. Other aspects of MMA may also affect state spending.

Possible Effects on Enrollment. When MMA was enacted, it was expected that outreach for the drug benefit would result in a "woodwork" effect, with an expansion in the population enrolling in Medicaid and Medicaid savings programs. Current Medicaid enrollment figures are not available, however, it does not appear that this has occurred to a major extent. This may reflect, in part, the fact that there are an estimated 3 million persons potentially eligible for the LIS who have failed to enroll.

Possible Long Term Implications. New enrollees who are full dual eligibles are 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.[50]

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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[49] National Governors Association, letter from Governors Jon S. Corzine and Jim Douglas, to Michael O. Leavitt, Secretary of HHS, Feb. 12, 2007.

[50] 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 2007, CBO provided updated estimates of the drug benefit, including its estimates relating to low-income participation. These estimates were lower than those provided a year earlier and reflect both the fact that overall, beneficiaries are tending to enroll in lower cost plans, and Part D enrollment, particularly for LIS enrollees is lower than expected.

The March 2007 CBO baseline estimated Part D Medicare spending at $47.0 billion in FY2007, $52.2 billion in FY2008, and rising to $78.1 billion in FY2011; and that spending under the low-income subsidy provisions would total $15.2 billion in FY2007, $15.9 billion in FY2008, and rise to $24.3 billion in FY2011. It estimated that there would be 9.2 million low-income subsidy enrollees in FY2007, 9.7 million in FY2008, and rise to 10.5 million by FY2011. It also estimated that payments by the states under the "clawback" provision would total $7.1 billion in FY2007, $7.5 billion in FY2008, $8.1 billion in FY2009, $8.8 billion in FY2010, and $9.6 billion in FY2011.[51]

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.[52] These estimates were subsequently revised.[53]

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[51] *Fact Sheet for CBO's March 2007 Baseline: Medicare*, March 2007.

[52] 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.

[53] 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.

CMS estimated that as of January 16, 2007, 39.0 million persons had drug coverage; of the total, 27.2 million persons had Part D drug coverage, 6.9 million were covered under the retiree drug subsidy program, and 4.9 million persons had creditable coverage through another source such as through the Department of Veterans Affairs.

As of the same date, CMS estimated that 13.2 million persons were eligible for the LIS. Of these, 10 million had coverage through Part D or some other source, with 9.2 million covered under Part D itself (of which 6.9 million were automatically deemed eligible). CMS estimated that approximately 0.03 million LIS approved beneficiaries would have their enrollments facilitated in the next round, leaving 3.27 million LIS-eligible beneficiaries not enrolled. CMS noted that the 3.27 figure may include some LIS-eligible persons who had not yet regained their deemed status or been approved for the LIS by the SSA, but were still receiving coverage through Part D.[54]

CMS also reported that 632,000 persons automatically deemed eligible for LIS in 2006, lost their automatic status in 2007. It reported that as of January 2007, 35% had either regained their deemed status or had applied for and qualified for the LIS. It stated it was paying close attention to this population group. It did not state what portion of the remaining 65% were still enrolled in Part D though no longer eligible for LIS and what portion had dropped their participation. As noted earlier, any individual determined LIS-eligible at any point during 2007 will be able to enroll in a plan at that point without a late enrollment penalty.

Current Concerns

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 on an individual's income level. Further, beneficiaries wishing to access the drug benefit are only able to do so through enrollment in a private standalone drug plan or a managed care plan with a drug benefit.

Implementation of the new program, particularly enrolling the low-income population, proved challenging. The main concern now is the fact that, despite extensive outreach efforts, not all persons potentially eligible for low-income subsidies have enrolled in the program. It is not immediately clear why some individuals have failed to enroll though several factors including lack of program awareness, the nature of the application process itself, and the assets limits presumably each play a role. There is also concern regarding the current situation of persons who lost their deemed eligibility status in 2007.

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[54] 1) CMS, *Medicare Drug Plans Strong and Growing*, press release, January 30, 2007.; and 2) [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/02_EnrollmentData.asp#TopOfPage].

It is hoped that the continued waiver of both the enrollment deadline and the enrollment penalty for the low-income population in 2007 will encourage more persons to enroll during the remainder of the year.

Legislative Activity

Actions Related to FY2009 Budget

It is expected that the 110th Congress will continue to monitor program implementation, particularly as it affects the low-income population. Recent letters to the Chairman of the Senate and House Budget Committees (as required by the Congressional Budget Act of 1974) provide an overview of expected activities this year.

On March 2, 2007, Senators Baucus and Grassley, Chairman and Ranking Member, respectively, of the Senate Finance Committee, sent a letter to the Senate Budget Committee. The letter noted that an estimated three-fourths of beneficiaries who remain without prescription drug coverage would likely qualify for LIS. Therefore the letter stated that consideration should be given toward investing more in outreach programs. As a complement to the effort, the letter stated that the current low-income application should be reviewed to ensure that it obtained the necessary information without being overly burdensome, and that it provides sufficient instruction to respond to the questions. The letter also stated that the asset test should be revisited. The Senators stated that consideration should be given to removing or increasing the current asset limits.

Two committees have jurisdiction over the Part D program on the House side. Congressman Rangel, Chairman of the House Ways and Means Committee, sent a letter to the House Budget Committee on February 28, 2007. The letter stated the intention to monitor implementation of MMA and to conduct oversight of Part D. Congressman Dingell, Chairman of the House Energy and Commerce Committee, sent a letter March 1, 2007, commenting on the President's budget proposals. It criticized the budget for failing to include proposals to remedy problems with the Part D benefit.

Pending Legislation

Several bills have been introduced to amend Part D. On March 15, 2007, Congressman Doggett, together with 157 cosponsors, introduced H.R. 1536, the Prescription Drug Coverage Now Act of 2007. This legislation would require the Secretary to provide for an expedited process for the qualification of individuals for low-income assistance. The process would require newly enrolling persons to receive information about the low-income subsidy and permit them to opt into the expedited process by requesting the Commissioner of Social Security to screen for subsidy eligibility through a request to the Secretary of the Treasury. The Secretary would be required to make a similar request through the Commissioner and the Secretary of the Treasury for persons enrolled before implementation of this process.

The Secretary of the Treasury would, upon written request to the Commissioner, disclose to the Commissioner whether an identified individual was likely to be eligible for subsidy assistance and the amount of premium and cost-sharing assistance for which the person would qualify.

The Secretary would be required to notify persons identified as potentially eligible (but not otherwise determined eligible) and provide them with information on the amount of subsidies and enrollment opportunities. The notification would include a one-page attestation form for income and assets. The form would not require submission of additional documentation regarding income or assets. It would permit the appointment of a personal representative and would allow for the specification of a language other than English preferred for subsequent communications. If an individual in good faith executed an attestation and was subsequently found ineligible, no recovery would be made for subsidies improperly paid.

The notification would also provide information on the State Health Insurance Program (SHIP) from which the individual could obtain assistance. If the individual did not respond to the notification, attempts would be made to follow up.

PDP and MA-PD applications would be required to provide an option for persons to opt-in to the expedited process.

H.R. 1536 also would amend current resources standards. By law, full subsidy eligible individuals had assets limits in 2006 equal to three times the amount of such standards for the supplemental security income (SSI) program (i.e., $6,000 for a single and $9,000 for a couple), increased in future years by the percentage increase in the CPI (i.e., $6,120 for a single and $9,190 for a couple in 2007). These would be raised to six times the SSI level in 2008 (i.e., $12,000 for a single and $18,000 for a couple), with future increases tied to CPI increases.

Current law resource limits for other low-income persons were $10,000 for a single and $20,000 for a couple in 2006, raised by the CPI in future years (i.e., $10,210 for a single and $20,410 for a couple in 2007). These would be raised to $27,500 for a single and $55,000 for a couple in 2008, with future increases tied to CPI increases.

H.R. 1536 would further specify that the value of life insurance polices and balances in pensions or retirement plans would not be considered in calculating resources; and in-kind support and maintenance would not be counted as income.

Additionally, H.R. 1536 would 1) index any current deductible and cost-sharing amounts applicable for the low-income to the increase in the CPI (not the increase in per capita spending as is the case for those not eligible for full subsidies); 2) specify that receipt of low-income subsidy benefits would have no impact on eligibility for other programs; 3) require the Commissioner of Social Security, as part of making subsidy determinations, to screen for eligibility for Medicare Savings programs; 4) establish a 90-day special enrollment period, beginning on the date the individual received notification of subsidy eligibility; and a facilitated enrollment

process for persons who failed to enroll in a plan; and 5) waive of late enrollment penalties for subsidy eligible individuals, beginning effective 2008.

As of this writing, it is too early to predict whether there will be any LIS-related legislation enacted into law this year.