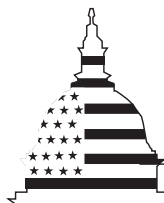


May 2007

MEDICARE PART D

Challenges in Enrolling New Dual-Eligible Beneficiaries



G A O

Accountability * Integrity * Reliability



Highlights of [GAO-07-272](#), a report to congressional requesters

Why GAO Did This Study

Since January 1, 2006, all dual-eligible beneficiaries—individuals with both Medicare and Medicaid coverage—must receive their drug benefit through Medicare’s new Part D prescription drug plans (PDP) rather than from state Medicaid programs. GAO analyzed (1) current challenges in identifying and enrolling new dual-eligible beneficiaries in PDPs, (2) the Centers for Medicare & Medicaid Services’ (CMS) efforts to address challenges, and (3) federal and state approaches to assigning dual-eligible beneficiaries to PDPs. GAO reviewed federal law, CMS regulations and guidance and interviewed CMS and PDP officials, among others. GAO also made site visits to six states to learn about the enrollment of dual-eligible beneficiaries from the state perspective.

What GAO Recommends

GAO made six recommendations to CMS. CMS has taken steps to implement some of them, including notifying beneficiaries of their right to reimbursement and monitoring the number of individuals provided retroactive coverage. However, CMS disagreed with GAO’s other recommendations, including monitoring PDP reimbursements to beneficiaries, mitigating the risks of information system changes, and facilitating states’ access to certain drug-related information. GAO maintains its support for these recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-07-272.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Kathleen King at (202) 512-7119 or kingk@gao.gov or David Powner at (202) 512-9286 or pownerd@gao.gov.

MEDICARE PART D

Challenges in Enrolling New Dual-Eligible Beneficiaries

What GAO Found

CMS’s enrollment procedures and implementation of its Part D coverage policy generate challenges for some dual-eligible beneficiaries, pharmacies, and the Medicare program. A majority of new dual-eligible beneficiaries—generally those on Medicare who have not yet signed up for a PDP and who become eligible for Medicaid—may be unable to smoothly access their drug benefit for at least 5 weeks given the time it takes to enroll them in PDPs and communicate information to beneficiaries and pharmacies. Pharmacies also may be affected adversely when key information about a beneficiary’s dual eligibility is not yet processed and available. When dispensing drugs during this interval, pharmacies may have difficulty submitting claims to PDPs and accurately charging copayments. In addition, Medicare pays PDPs to provide these beneficiaries with several months of retroactive coverage but, until March 2007, CMS did not inform beneficiaries of their right to be reimbursed for drug costs incurred during these periods. CMS does not monitor its payments to PDPs for retroactive coverage or the amounts PDPs have reimbursed dual-eligible beneficiaries. Medicare paid PDPs millions of dollars in 2006 for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs.

CMS has taken steps to address challenges associated with enrolling dual-eligible beneficiaries in PDPs. CMS has implemented a policy to prevent a gap in prescription drug coverage for those new dual-eligible beneficiaries whose Part D eligibility is predictable—Medicaid beneficiaries who subsequently qualify for Medicare. We estimate this group represents about one-third of new dual-eligible beneficiaries. In August 2006, CMS began operating a prospective enrollment process that should allow the agency and its Part D partners time to complete the enrollment processes and notify these beneficiaries before their effective enrollment date. Also, CMS is making changes to improve the efficiency of key information systems involved in the enrollment process. While the agency is performing some information systems testing, it is not planning to perform testing of the interactions of key information systems collectively, which is crucial to mitigating the inherent risks of system changes.

Under federal law, CMS is required to assign dual-eligible beneficiaries to PDPs based on PDP premiums and geographic area. State Medicaid agency officials and others assert that this assignment method often places dual-eligible beneficiaries in PDPs that do not meet their drug needs. With CMS approval, Maine officials considered beneficiary-specific data to reassign nearly half of their dual-eligible beneficiaries to PDPs that better met their drug needs in late 2005. After the reassignment, the number of these dual-eligible beneficiaries whose PDP covered nearly all of their prescription drugs increased significantly. States choosing to make such reassignments in the future would need ready access to key information from PDPs. CMS contends that reassignments are not needed because beneficiaries may switch to drugs of equivalent therapeutic value or change plans at any time.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
DI	Disability Insurance
IRA	Intelligent Random Assignment
IT	information technology
MA	Medicare Advantage
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
NASMD	National Association of State Medicaid Directors
OIG	Office of Inspector General
PAAD	Pharmaceutical Assistance to the Aged and Disabled
PDP	prescription drug plan
SPAP	state pharmaceutical assistance program
SSA	Social Security Administration
SSI	Supplemental Security Income
TRR	Transaction Reply Report

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United States Government Accountability Office
Washington, DC 20548

May 4, 2007

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

The Honorable John D. Rockefeller IV
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Subcommittee on Health Care
Committee on Finance
United States Senate

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established a voluntary outpatient prescription drug benefit for Medicare—the federal health insurance program for elderly and certain disabled individuals—known as Medicare Part D.¹ This benefit is provided through prescription drug plans (PDP) sponsored by contracted private companies.² These private companies, termed sponsors, offer one or more benefit packages, through individual PDPs that charge monthly premiums that cover different drugs and have different beneficiary cost-sharing arrangements (such as copayments and deductibles). Medicaid is a jointly funded federal-state health care program that covers certain low-income families and low-income individuals who are aged or disabled. Medicaid beneficiaries receive their prescription drugs at no or low cost as part of

¹MMA, Pub. L. No. 108-173, tit. I, §101, et seq., 117 stat. 2066, 2071-2152 (2003) (adding new sections 1860D-1, et seq. and 1935 to the Social Security Act, to be codified at 42 U.S.C. §1395w-101, et seq. and 42 U.S.C. §1396u-5). For the remainder of the report, we will refer only to provisions of the Social Security Act when referencing MMA requirements.

²Drug coverage may also be provided through Medicare Advantage (MA) prescription drug plans. MA plans are Medicare's private health plan option, providing coverage of benefits beyond prescription drugs.

their Medicaid benefits.³ About 6 million people were eligible for both full Medicare and Medicaid benefits in December 2005 and more become eligible each month. For those who are dually eligible for both Medicare and Medicaid, known as full-benefit dual-eligible beneficiaries,⁴ the MMA required that drug coverage transition from Medicaid drug coverage to Medicare Part D drug coverage on January 1, 2006.⁵ Dual-eligible beneficiaries are generally poorer, are more likely to have extensive health care needs, and use more medications than other Medicare beneficiaries. To help dual-eligible beneficiaries and other low-income Medicare beneficiaries with the costs of prescription drug coverage, the MMA provided these individuals with a low-income subsidy that covers most of their out-of-pocket costs for Part D prescription drugs.⁶

The Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—has responsibility for assisting in the transition of dual-eligible beneficiaries' drug coverage from Medicaid to Medicare. In October and December 2005, CMS assigned each dual-eligible beneficiary who had not already signed up for a Part D plan to a PDP and notified these beneficiaries of their assignment. Part D prescription drug coverage for these beneficiaries was effective January 1, 2006. CMS also provided state pharmaceutical assistance programs (SPAP) with the ability to enroll or reassign their members to PDPs using additional criteria, with prior approval from CMS.⁷

The agency also developed contingency measures to help with administrative difficulties that could arise with the change in coverage. It established an enrollment contingency option to ensure that dual-eligible beneficiaries not yet enrolled in a PDP could get their prescriptions and that pharmacies would be reimbursed for those prescriptions. Also, CMS required PDPs to provide beneficiaries with a short-term supply of needed

³While drug coverage is an optional Medicaid benefit, all state Medicaid programs cover prescription drugs as part of their benefit package. In 2004, 40 state Medicaid programs and the District of Columbia had copayments for prescription drugs and 17 states had limits on the number of prescriptions that could be filled by the beneficiary.

⁴In this report, the term dual-eligible beneficiaries refers to full-benefit dual-eligible beneficiaries unless otherwise noted.

⁵Social Security Act §§ 1860D-1(a)(2), 1935(d).

⁶Social Security Act § 1860D-14.

⁷SPAPs are state-funded programs that provide financial assistance for prescription drugs to low-income elderly and disabled individuals.

drugs, known as a transition supply, if they were prescribed a drug that was not on their PDP's list of covered drugs, or formulary.

Shortly after the start of the program, the media reported that some dual-eligible beneficiaries encountered difficulties that limited their access to needed drugs. These included reports of dual-eligible beneficiaries not enrolled in a PDP, enrolled in more than one PDP, not correctly identified as a low-income beneficiary, charged incorrect copayments at the pharmacy, and unable to obtain drugs because of inadequate transition coverage. In February 2006, the Secretary of Health and Human Services reported that these problems potentially affected several hundred thousand dual-eligible beneficiaries.⁸ Some of these problems were the result of data transmission difficulties among the states, CMS, and PDP sponsors. Responding to a February 2006 survey by The Kaiser Family Foundation, 31 state Medicaid directors reported widespread problems affecting a significant number of dual-eligible beneficiaries.⁹ In response to the problems, 29 state Medicaid agencies and the District of Columbia's Medicaid agency interceded and provided temporary coverage to ensure dual-eligible beneficiaries had access to prescription drugs.

Each month CMS randomly assigns and enrolls new dual-eligible beneficiaries who are not already in a Part D plan.¹⁰ Of the 633,614 new dual-eligible beneficiaries that CMS automatically enrolled in 2006, most were Medicare beneficiaries who subsequently qualified for Medicaid, generally due to a loss of income and resources.¹¹ Others were Medicaid beneficiaries who subsequently qualified for Medicare, typically due to age or disability. In addition to new dual-eligible beneficiaries, some previously assigned dual-eligible beneficiaries may be reassigned each benefit year. In fall 2006, CMS reassigned about 193,000 dual-eligible

⁸See Mike Leavitt, *Secretary's One Month Progress Report on the Medicare Prescription Drug Benefit* (Washington, D.C.: Department of Health and Human Services, Feb. 1, 2006).

⁹See Vernon Smith, Kathleen Gifford, Sandy Kramer, and Linda Elam, *The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation* (Washington, D.C.: The Henry J. Kaiser Family Foundation, Feb. 2006).

¹⁰In addition to assigning and enrolling new dual-eligible beneficiaries on a monthly basis, CMS assigns and enrolls existing dual-eligible beneficiaries who have disenrolled from a Part D plan without re-enrolling in another one.

¹¹The 633,614 excludes those Medicare beneficiaries who were previously enrolled by CMS prior to becoming full-benefit dual-eligible beneficiaries. In 2006, CMS chose to enroll about 1.5 million of these Medicare beneficiaries in PDPs under CMS's facilitated enrollment process, which is outside the scope of this report.

beneficiaries to new PDPs for the 2007 benefit year. Consequently, the challenges of ensuring prompt and accurate Part D enrollment are ongoing.

Given the reported problems that occurred during the early months of the Part D program, you raised questions about whether difficulty obtaining prescription drugs could continue to be a problem for many newly identified dual-eligible beneficiaries. In this report, we examine (1) current challenges in identifying and enrolling new dual-eligible beneficiaries in PDPs, (2) CMS's efforts to address challenges in enrolling dual-eligible beneficiaries, (3) federal and state approaches to assigning dual-eligible beneficiaries to PDPs, and (4) CMS's actions to ensure that PDPs implement effective transitional drug coverage following enrollment.

To address these issues, we reviewed relevant federal laws and regulations and guidance provided by CMS to state Medicaid agencies, PDPs, and pharmacies on their respective roles in the Medicare Part D benefit, CMS documents on the interaction of key information systems, and the model contract between CMS and PDP sponsors.¹² We also interviewed CMS officials, including those responsible for information systems, CMS contractors responsible for maintaining key information systems, Social Security Administration (SSA) officials,¹³ state Medicaid officials, and representatives of pharmacy associations and long-term care provider associations.¹⁴ We also interviewed representatives from five PDP sponsors that represented about 54 percent of dual-eligible PDP enrollment as of June 3, 2006.¹⁵ Each of these sponsors offered a PDP that was eligible to receive assignments of dual-eligible beneficiaries in 2006. To learn about alternative methods of assigning Medicare beneficiaries to PDPs, we also interviewed representatives of SPAPs.

¹²See also GAO, *Medicare: Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage*, [GAO-06-278R](#) (Washington, D.C.: Dec. 16, 2005).

¹³The SSA pays retirement, disability, and survivors' benefits to workers and their families.

¹⁴For purposes of this report, we use the term pharmacy associations to include both associations that represent pharmacies and those that represent pharmacists.

¹⁵Although dual-eligible beneficiaries may obtain drug coverage through either PDPs or MA plans, we focused on stand-alone PDPs. More than 90 percent of dual-eligible beneficiaries are enrolled in PDPs, rather than MA plans. In addition, CMS only enrolls dual-eligible beneficiaries into stand-alone PDPs, unless the individual was previously enrolled in a MA plan.

We also conducted site visits in six states—California, Maine, Maryland, Michigan, New Jersey, and Texas—to learn about the transition of dual-eligible beneficiaries from the perspective of state Medicaid agencies, pharmacies, and long-term care providers. Together, these states accounted for 28 percent of all dual-eligible beneficiaries enrolled in a PDP in May 2006. In selecting the states, we chose states that represented a range in the number of dual-eligible beneficiaries, the number of PDPs to which CMS assigned dual-eligible beneficiaries, state involvement with PDP assignment, and state size.¹⁶ Information from the six states cannot be generalized to every state’s experience with the Part D program because each state Medicaid program is different. To assess the reliability of Maine’s data on the reassignment of dual-eligible beneficiaries—the only state in our sample to have such information—we talked with Maine Medicaid agency officials and state contractors about how the analyses were conducted and reviewed documentation of the methodology. We determined that the data were sufficiently reliable for the purposes of this report. We conducted our work from March 2006 through April 2007 in accordance with generally accepted government auditing standards.

Results in Brief

CMS’s enrollment procedures and implementation of its Part D coverage policy generate challenges for some dual-eligible beneficiaries, pharmacies, and the Medicare program. A majority of new dual-eligible beneficiaries enrolled by CMS—generally those on Medicare who have not yet signed up for a PDP and who become eligible for Medicaid—may be unable to smoothly access their drug benefit for at least 5 weeks given the timing of the steps to enroll dual-eligible beneficiaries in PDPs and communicate information to beneficiaries and pharmacies. Pharmacies also may be affected adversely when key information about a beneficiary’s dual eligibility is not yet processed in the appropriate eligibility and enrollment systems. When dispensing drugs to dual-eligible beneficiaries during this interval, pharmacies may have difficulty submitting claims to PDPs and accurately charging beneficiaries for copayments. In addition, under CMS policy, Medicare pays PDPs to provide these dual-eligible beneficiaries with retroactive coverage that extends for several months. However at the time of our review, CMS did not inform beneficiaries of

¹⁶We also considered the degree of difficulty with the January 2006 transition as reported in a survey of state Medicaid agencies conducted for The Henry J. Kaiser Family Foundation. See Vernon Smith, Kathleen Gifford, Sandy Kramer, and Linda Elam, *The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation* (Washington, D.C.: The Henry J. Kaiser Family Foundation, Feb. 2006).

their right to be reimbursed for drug expenses incurred during retroactive coverage periods. After reviewing a draft of this report, CMS revised the enrollment notification letters informing dual-eligible beneficiaries of their eligibility for reimbursement. Also, CMS does not monitor its payments to PDPs for providing retroactive coverage or the amounts PDPs have reimbursed dual-eligible beneficiaries. GAO found that Medicare paid PDPs millions of dollars in 2006 for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs.

CMS has recently taken steps to address identified problems associated with enrolling dual-eligible beneficiaries. The agency has implemented a change in policy that should prevent a gap in drug coverage for those new dual-eligible beneficiaries whose Part D eligibility can be predicted. This group—about one-third of new dual-eligible beneficiaries enrolled by CMS in a PDP—consists of Medicaid beneficiaries whose drug coverage ends under Medicaid when they also become Medicare eligible. In August 2006, CMS began operating a prospective enrollment process that allows the agency and its Part D partners the time needed to complete the enrollment processes and notify this group of beneficiaries before PDP enrollment becomes effective. CMS has also taken steps to improve the information available to pharmacies when serving dual-eligible beneficiaries who do not have evidence of PDP enrollment. In addition, CMS is redesigning and integrating key information systems to reduce redundancies, synchronize data, and increase the efficiency of the systems involved in the enrollment process. While the agency is performing certain types of systems testing to ensure that these changes are effectively implemented, it is not planning to test the interactions of key information systems collectively and their interfaces (commonly referred to as end-to-end testing).

As required under the MMA and implementing regulations, when a dual-eligible beneficiary has not chosen a Part D plan, CMS randomly assigns and enrolls dual-eligible beneficiaries to a PDP. The only criteria CMS may use in assigning these dual-eligible beneficiaries are the PDP's monthly premium and the geographic location of the PDP. This is designed to ensure that PDP sponsors enroll an approximately equal number of beneficiaries. In a small number of cases, beneficiaries were enrolled in a PDP that did not serve their geographic location because CMS used an address from SSA that did not accurately reflect where they lived. In response to a draft of this report, CMS made changes to correct this problem. In late 2005, with approval from CMS, officials in Maine reassigned nearly half of the state's dual-eligible beneficiaries for the initial transition to Medicare Part D using additional criteria they believed to be

more appropriate for beneficiaries' individual needs. A 2005 state analysis showed that CMS's random assignment resulted in about one in five dual-eligible beneficiaries having formulary match rates—the percentage of a beneficiary's medications that appeared on the PDP formulary—of less than 20 percent. After reassigning beneficiaries to eligible PDPs using drug utilization and pharmacy preference information, these beneficiaries' match rates approached 100 percent. Maine officials noted that, to conduct yearly reassignments for the dual-eligible population, they needed up-to-date beneficiary drug utilization and formulary information from PDP sponsors. CMS and PDP sponsors informed us, however, that reassigning dual-eligible beneficiaries to PDPs using additional criteria is not necessary because beneficiaries may switch to medications of equivalent therapeutic value or change plans at any time during the year.

CMS actions to address problems associated with PDP implementation of pharmacy transition processes led to a more uniform application of transition processes; however, some dual-eligible beneficiaries remain confused. Under PDP transition processes, beneficiaries should be provided temporary coverage of existing prescriptions, regardless of whether the drug is on the PDP's formulary, to allow them time to contact their physician about switching to a medication on their PDP's formulary or obtaining a formulary exception from their PDP. In early 2006, CMS officials learned that the way in which some PDP sponsors implemented their transition policies adversely affected beneficiaries' ability to obtain transition drug supplies. CMS responded by issuing a series of memoranda to PDP sponsors to clarify its expectations. Representatives of pharmacy and long-term care associations, state Medicaid agencies, and PDP sponsors told us that the problem of uneven availability of transition drug coverage has largely been resolved. They noted, however, that dual-eligible beneficiaries remain unaware of the implications of the transition supply and are not using the transition period to address formulary issues. As a result, after receiving a transition supply, these beneficiaries often return to the pharmacy the following month and may encounter problems refilling these same prescriptions. For 2007, CMS has added specific requirements to its contract with PDP sponsors with respect to providing transition drug coverage to new enrollees and for notifying beneficiaries and pharmacists about transitional coverage.

We recommend that, to improve the process of enrolling dual-eligible beneficiaries in PDPs, the CMS Administrator take actions to inform dual-eligible beneficiaries of their right to reimbursement, track the number of new dual-eligible beneficiaries receiving retroactive coverage, determine the magnitude of payments to PDPs for retroactive coverage periods and

monitor PDP reimbursements to dual-eligible beneficiaries, mitigate the risks associated with implementing changes to Part D information systems by conducting additional testing, ensure dual-eligible beneficiaries are enrolled in a PDP that serves the geographic area where they live, and facilitate data sharing between PDPs and authorized states that choose to reassign their dual-eligible beneficiaries using alternative methods.

In comments on a draft of this report, CMS objected to what it perceived as the overwhelmingly negative tone of our findings and stated that our discussion of retroactive coverage was overly simplified. Nevertheless, the agency stated that it was implementing three of our six recommendations to improve existing procedures; it disagreed with the remaining recommendations. We believe that our findings are balanced and accurate and our recommendations are appropriate. To clarify our message and to reflect information obtained through agency comments, we have modified portions of the first finding concerning the intervals associated with processing dual-eligible beneficiaries' enrollments and the fact that Medicare pays plans during periods when dual-eligible beneficiaries may be unlikely to seek reimbursement for drug costs.

Background

The Medicare Part D Program

Medicare Part D coverage is provided through private plans sponsored by dozens of health care organizations that may charge premiums, deductibles, and copayments for the drug benefit.¹⁷ All Part D plans must meet federal requirements with respect to the categories of drugs they

¹⁷The number of health care organizations sponsoring private plans was 79 in 2006 and more than 90 for 2007.

must cover and the extent of their pharmacy networks.^{18,19} They must offer the standard Medicare Part D benefit, or an actuarially equivalent benefit.²⁰ Beyond these requirements however, the specific formulary and pharmacy network of each PDP can vary.

Under the MMA, drug coverage for all dual-eligible beneficiaries transitioned from Medicaid to Medicare Part D, on January 1, 2006.²¹ The MMA requires CMS to assign dual-eligible beneficiaries to a PDP if they have not enrolled in a Part D plan on their own.²² CMS may only assign dual-eligible beneficiaries to PDPs serving their area with premiums at or below the low-income benchmark amount and must randomly assign individuals if there is more than one eligible PDP.²³ During October and December 2005, CMS randomly assigned to PDPs dual-eligible beneficiaries who had not already enrolled in a Part D plan. The agency

¹⁸Under the MMA, PDPs must cover drugs within each therapeutic category and class of Part D drugs. PDPs may not cover the following nine categories of drugs as the MMA excluded these categories from Medicare Part D coverage: (1) agents used for anorexia, weight loss, or weight gain; (2) agents used to promote fertility; (3) agents used for cosmetic purposes or hair growth; (4) agents used for the symptomatic relief of coughs or colds; (5) prescription vitamins and minerals, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer seeks to require associated tests or monitoring be purchased from the manufacturer or their designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines. State Medicaid agencies may provide coverage of drugs in these excluded drug categories to their dual-eligible beneficiaries under the Medicaid program. Social Security Act §§1860D-2(e), 1860D-4(b)(3)(C), 1935(d)(2).

¹⁹All PDPs must have a contracted pharmacy in their network that is within 2 miles of 90 percent of urban beneficiaries, 5 miles of 90 percent of suburban beneficiaries, and 15 miles of 70 percent of rural beneficiaries. Social Security Act §1860D-4(b)(1)(C); 42 C.F.R. §423.120.

²⁰The Part D standard benefit for 2007 includes a \$265 annual deductible, 25 percent coinsurance for total covered drug costs between \$265 and \$2,400, and 100 percent coinsurance for drug spending between \$2,401 and \$5,451.25. After a beneficiary incurs \$3,850 in covered out-of-pocket costs, catastrophic coverage begins and the beneficiary is responsible for modest cost-sharing. Each year the standard benefit is adjusted to account for the increase in average total drug expenses of Medicare beneficiaries. Actuarially equivalent coverage is coverage that is at least the same in value as the standard benefit, but may be structured differently, as approved by CMS.

²¹Social Security Act §1860D-1(a)(2).

²²Social Security Act §1860D-1(b)(1)(C). The formal name for this process is automatic enrollment.

²³Social Security Act §1860D-1(b)(1)(C); see also 42 C.F.R. § 423.34. The low-income benchmark is the average monthly beneficiary premium for all PDPs in a region, weighted by each plan's enrollment.

mailed notices to these beneficiaries informing them of their assignment and also that they could select a different PDP if they wished. If they did not switch from their assigned PDP by December 31, 2005, their assignment took effect, with coverage beginning January 1, 2006. CMS enrolled 5,498,604 dual-eligible beneficiaries during this first round of assignments and continues to assign new dual-eligible beneficiaries into PDPs on a monthly basis, when these beneficiaries do not independently enroll in a Part D plan.

For some dual-eligible beneficiaries, some drugs that were previously covered under Medicaid might not be covered by their Medicare PDP's formulary. Subject to certain parameters,²⁴ PDPs have the flexibility to set their own formularies and, as a result, PDPs vary in their inclusion of the drugs most commonly used by dual-eligible beneficiaries. According to a 2006 report by the Department of Health and Human Services, Office of Inspector General (OIG), one-fifth of dual-eligible beneficiaries were assigned to PDPs that provide coverage of all of the most commonly used drugs and one-third were assigned to PDPs that provide coverage of less than 85 percent of these drugs.²⁵ However, dual-eligible beneficiaries are allowed to switch to a different PDP at any time with coverage under a new PDP effective the following month.

In addition, to help ensure a smooth transition to Part D, CMS requires PDP sponsors to provide for a transition process for new enrollees whose

²⁴PDP formularies generally must cover at least two Part D drugs in each therapeutic category and class, except when there is only one drug in the category and class or when CMS has allowed the plan to cover only one drug in that category or class. 42 C.F.R. §423.120(b)(2). CMS may require coverage of more than two drugs in each category or class when the drugs provide therapeutic advantages or absence from a formulary may discourage enrollment in a plan. For example, CMS has designated six categories of drugs (antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant, and HIV/AIDS drugs) for which PDPs must cover "all or substantially all" of the drugs. See Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines – Formularies*, posted at http://www.cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp#TopOfPage, accessed January 19, 2007.

²⁵In its comments on the OIG report, CMS stated that the methodology OIG used was flawed because it was based on a list of 178 drugs commonly used by dual-eligible beneficiaries rather than an examination of actual use of drugs at the individual beneficiary level. CMS also stated that because all formularies cover multiple drugs in each therapeutic class, all beneficiaries have access to drugs that are very similar to their current medications. See Department of Health and Human Services, Office of Inspector General, *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*, OEI-05-06-00090 (Washington, D.C.: Jan. 2006).

current medications may not be included in their PDP's formulary.²⁶ For 2006, CMS recommended that PDP sponsors should fill a one-time transition supply of nonformulary drugs in order to accommodate the immediate need of the beneficiary. In particular, CMS suggested that PDPs provide at least a 30-day transition supply to all beneficiaries and a 90- to 180-day transition supply for residents in long-term care facilities.

Dual-Eligible Beneficiaries

Dual-eligible beneficiaries are a particularly vulnerable population. Totalling roughly 6.2 million in January 2006, they account for about 15 percent of all Medicaid beneficiaries and 15 percent of all Medicare beneficiaries. In general, these individuals are poorer, tend to have far more extensive health care needs, have higher rates of cognitive impairments, and are more likely to be disabled than other Medicare beneficiaries. A majority of dual-eligible beneficiaries live in the community and typically obtain drugs through retail pharmacies. Nearly one in four dual-eligible beneficiaries reside in a long-term care facility and obtain their drugs through pharmacies that specifically serve long-term care facilities.

While most Medicare beneficiaries enrolled in a PDP pay monthly premiums, deductibles, and other cost-sharing as part of their benefit package, the Medicare Part D program pays a substantial proportion of dual-eligible beneficiaries' cost-sharing obligations through its low-income subsidy program.²⁷ For dual-eligible beneficiaries, Medicare pays the full amount of the monthly premium that nonsubsidy eligible beneficiaries normally pay, up to the level of the low-income benchmark premium. Medicare Part D also covers most or all of the prescription copayments: dual-eligible beneficiaries pay from \$1 to \$5.35 copayments per prescription filled in 2007, with the exception of those in long-term care facilities who have no copayments. In addition, dual-eligible beneficiaries are not subject to a deductible or the so-called "donut hole."²⁸

In addition to dual-eligible beneficiaries, the Part D low-income subsidy is available to other low-income Medicare beneficiaries. Some of these other

²⁶42 C.F.R. § 423.120(b)(3).

²⁷See Social Security Act §1860D-14.

²⁸This refers to the fact that the standard Part D benefit provided no coverage for total covered drug expenditures between \$2,251 and \$5,100 for 2006, shifting to between \$2,401 and \$5,451.25 in 2007.

Medicare beneficiaries must apply for the subsidy through the SSA or a state Medicaid agency. The subsidy is available on a sliding scale, according to income and resources. Dual-eligible beneficiaries are automatically entitled to the full subsidy amount and do not need to apply independently for the subsidy.

An individual can become a dual-eligible beneficiary in two main ways. First, Medicare beneficiaries can subsequently qualify for Medicaid. This occurs when their income and resources decline below certain thresholds, and they enroll in the Supplemental Security Income (SSI) program,²⁹ or they incur medical costs that reduce their income below certain thresholds. CMS data indicate that roughly two-thirds of the 633,614 dual-eligible beneficiaries the agency enrolled in 2006 were Medicare beneficiaries who subsequently qualified for Medicaid, and had not already signed up for a PDP on their own.³⁰ According to CMS officials, it is not possible to predict the timing of dual-eligibility for these individuals because determining Medicaid eligibility is a state function.

Second, Medicaid beneficiaries can subsequently become eligible for Medicare by either turning 65-years-old or by completing their 24-month disability waiting period.³¹ This group represents approximately one-third of the new dual-eligible beneficiaries enrolled by CMS in PDPs. State Medicaid agencies can generally predict when this group of individuals will become dually eligible.

²⁹In most states, beneficiaries who qualify for cash assistance from SSI—a cash assistance program for aged, blind, and disabled individuals with limited income and resources—automatically qualify for full Medicaid benefits. In 39 states and the District of Columbia, SSI eligibility assures an individual’s eligibility for Medicaid benefits. Eleven state Medicaid agencies either (1) use more restrictive income or asset requirements than SSI for Medicaid eligibility or (2) require a separate Medicaid application/determination than the SSI application/determination.

³⁰Beneficiaries already enrolled in a PDP are allowed to stay in the same PDP after they become dually eligible. They are not included in the two-thirds number because CMS did not enroll them when they became dually eligible for Medicare and Medicaid.

³¹Under Social Security Disability Insurance (DI), which assists people who worked but became disabled before their retirement age, individuals are eligible for Medicare coverage after they have received DI cash benefits for 24 months.

Systems and Steps Involved in the Identification and Enrollment of Dual-Eligible Beneficiaries

Multiple parties and multiple information systems are involved in the process of identifying and enrolling dual-eligible beneficiaries in PDPs. In addition to CMS, the SSA, state Medicaid agencies, and PDP sponsors play key roles in providing information needed to ensure that beneficiaries are identified accurately and enrolled. SSA maintains information on Medicare eligibility that is used by CMS and some states. State Medicaid agencies are responsible for forwarding to CMS lists of beneficiaries who the state believes to be eligible for both Medicare and Medicaid. PDP sponsors maintain information systems that are responsible for exchanging enrollment and billing information with CMS.

For the most part, CMS adapted existing information systems used in the administration of other parts of the Medicare program to perform specific functions required under Part D. In addition, CMS worked with the pharmacy industry to develop a tool specifically to aid pharmacies in obtaining billing information needed to process claims for dual-eligible beneficiaries without enrollment information. The principal systems supporting the Part D program are as follows:

- *The Medicare eligibility database.*³² This system serves as a repository for Medicare beneficiary entitlement, eligibility, and demographic data. In the enrollment process for dual-eligible beneficiaries, the database is used by CMS to provide up-to-date information to verify the status of dual-eligible beneficiaries, as well as to determine subsidy status and make assignments to PDPs. It also provides data to other CMS systems, SSA, state Medicaid agencies, PDPs, and pharmacies.
- *The enrollment transaction system.*³³ This system is used to enroll beneficiaries in PDPs. In addition, it informs PDPs about a beneficiary's subsidy status and copayment information, calculates Medicare payments to PDPs for each covered enrollee, and processes changes in PDP enrollment, including those elected by the beneficiary.
- *The eligibility query.*³⁴ This tool is used by pharmacies to obtain Part D billing information from the Medicare eligibility database. When filling a prescription for a beneficiary who does not have proof of Part D enrollment or eligibility, a pharmacy submits a request for billing

³²This system's official name is the Medicare Beneficiary Database.

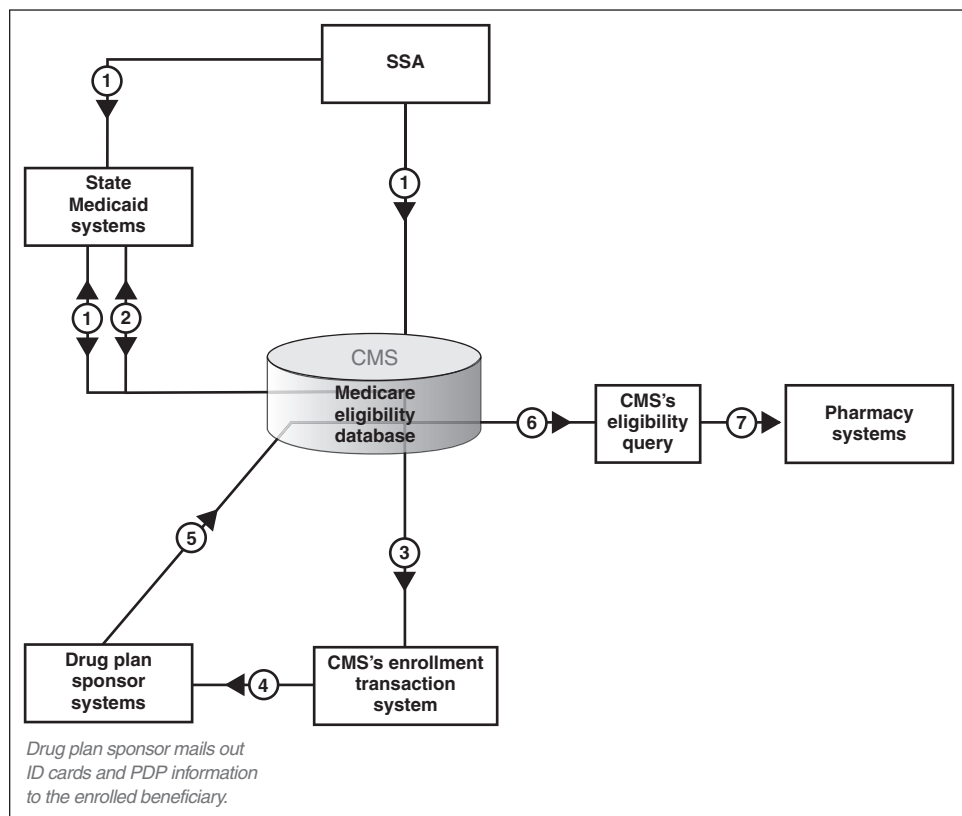
³³This system's official name is the Medicare Advantage Prescription Drug system.

³⁴This tool's official name is the E-1 query.

information using the eligibility query. In response, the pharmacy receives information on the beneficiary's PDP enrollment, including the data necessary to bill the beneficiary's PDP for the drugs dispensed.

The process of enrolling dual-eligible beneficiaries requires several steps; it begins when the state Medicaid agency identifies new dual-eligible beneficiaries and ends when PDPs make billing information available to pharmacies. (For more detailed information on the steps involved in identifying and enrolling dual-eligible beneficiaries, see app. I.) The key information systems (see fig. 1) and steps in identifying and enrolling dual-eligible beneficiaries are the following.

Figure 1: Overview of the Major Systems and Steps Used to Enroll Dual-Eligible Beneficiaries in PDPs



Source: GAO.

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1. State Medicaid agencies obtain Medicare eligibility information from SSA or request data from CMS's Medicare eligibility database and match that information against their own Medicaid eligibility files. The state Medicaid agencies compile comprehensive files identifying all dual-eligible beneficiaries, known as the dual-eligible files.³⁵ CMS receives Medicare eligibility information from SSA daily.
 2. State Medicaid agencies send CMS the dual-eligible files and CMS matches the files against data in its Medicare eligibility database to verify each individual's dual eligibility. The agency sends a response file back to each state that includes the results of the matching process for each submitted individual.
 3. Those dual-eligible beneficiaries who were matched are considered eligible for the full low-income subsidy and the Medicare eligibility database sets the copayment information accordingly. This process is referred to as deeming. The Medicare eligibility database also assigns beneficiaries not already enrolled in a Part D plan to PDPs that operate in regions that match the beneficiary's official SSA address of record. Both the deeming and assignment information are sent to the enrollment transaction system to be processed.
 4. The enrollment transaction system processes the deeming and assignment information in order to complete the enrollment and notifies the PDPs of those dual-eligible beneficiaries who have been enrolled in their PDP and their copayment amounts.
 5. PDPs process the resulting enrollment, assign the standard billing information, and send this information to the Medicare eligibility database. In addition, the PDPs mail out ID cards and PDP information to the enrolled beneficiary.
 6. The Medicare eligibility database transmits the PDP's billing information to the eligibility query system.
 7. Using the eligibility query, pharmacies can access the billing information needed to fill prescriptions and bill them to the assigned PDP if beneficiaries lack their enrollment information.

³⁵Dual-eligible files contain both newly identified dual-eligible beneficiaries and those who were previously identified.

Implementation of Part D Information Systems

Under tight time frames, CMS and its partners integrated information systems to support the Part D program. To support the Part D program, CMS pieced together existing information systems that had related Medicare functions.³⁶ In addition, information systems belonging to state Medicaid agencies and PDPs had to integrate with CMS information systems and CMS did not establish formal agreements with these partners until the time of implementation. Final regulations for the program were not issued until January 28, 2005, and business requirements for the program were not finalized until March 2005. Thus, there was little time for testing given that requirements and agreements were so late in being solidified.

A number of information systems problems surfaced in the early months of the program. These problems included logic errors in the enrollment process which generated cancellations to PDPs instead of enrollments, the eligibility query being overwhelmed by the number of pharmacy inquiries, and CMS difficulties matching data submitted by the state Medicaid agencies to information in the Medicare eligibility database. These problems can be attributed, in part, to poor systems testing. Because of tight time frames associated with implementing Part D, robust system-level and end-to-end testing did not occur.³⁷

In January 2006, CMS contracted with EDS, an information technology consulting company, to identify opportunities for improvement in the information systems and services for Medicare Part D. EDS's report findings and observations addressed many overarching challenges in the information systems infrastructure supporting the program, including the observation that the aggressive time frame for implementation did not allow sufficient time for end-to-end testing.³⁸ CMS is redesigning key information systems involved in the enrollment process in order to improve the efficiency of these systems.

³⁶According to CMS, an effort to design, test, and implement a system specifically designed to support a program of the magnitude of Part D would take years.

³⁷End-to-end testing is performed to verify that a defined set of interrelated systems that collectively support an organizational core business function interoperate as intended in an operational environment. The interrelated systems include not only those owned and managed by the organization, but also the external systems with which they interface.

³⁸See Claude H. Snow, Jr., *Opportunities for Improving Enrollment and Eligibility Processes and Systems in the Medicare Part D Prescription Drug Program: An Assessment* (prepared by EDS for the Centers for Medicare & Medicaid Services, Mar. 2006).

Enrollment Processes and Coverage Policy Generate Challenges for Dual-Eligible Beneficiaries, Pharmacies, and the Medicare Program

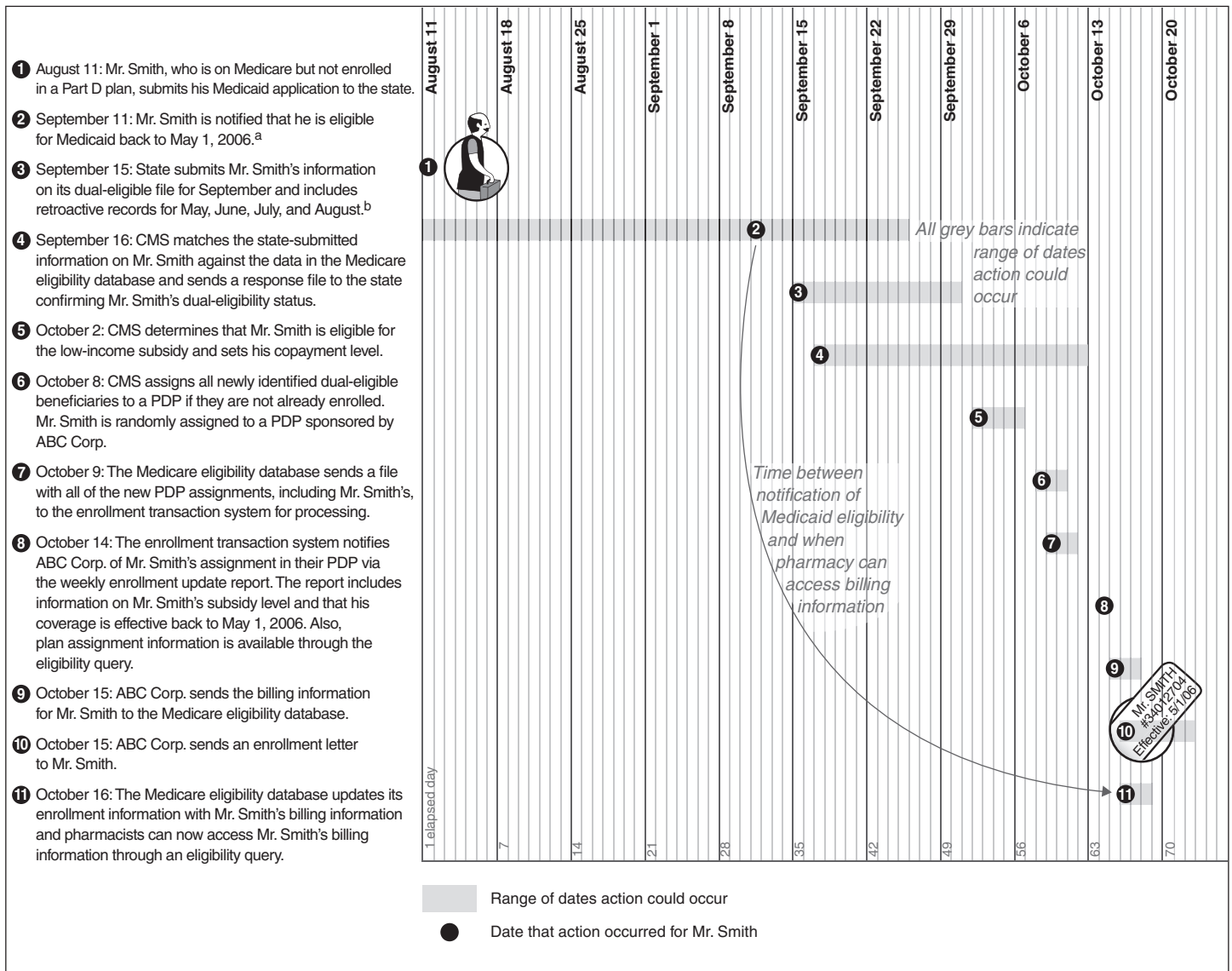
CMS's enrollment processes and implementation of its Part D coverage policy generate challenges for some dual-eligible beneficiaries, pharmacies, and the Medicare program. Because the interval between notification of Medicaid eligibility and completion of the Part D enrollment process can extend at least 5 weeks, some dual-eligible beneficiaries—those previously on Medicare who subsequently become eligible for Medicaid—may be unable to smoothly access their Part D benefits during this interval. At the same time, pharmacies that are unable to obtain up-to-date information about a dual-eligible beneficiary's enrollment are likely to experience difficulties billing PDPs. In addition, CMS has tied dual-eligible beneficiaries' effective date of Part D eligibility to the date of Medicaid eligibility, providing for several months of retroactive Medicare benefits. Although the Medicare program pays PDP sponsors for the period of retroactive coverage, beneficiaries were not informed of their right to reimbursement for drug costs incurred during this period. GAO found that Medicare paid PDPs an estimated \$100 million in 2006 for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs.

CMS's Enrollment Processes Can Create Difficulties for Some Dual-Eligible Beneficiaries

The timing of steps to enroll dual-eligible beneficiaries in Part D and to make billing information available to pharmacies generates a gap between the date beneficiaries are notified of their dual eligibility status and the date they receive their enrollment information. As a result, some new dual-eligible beneficiaries may have difficulty obtaining their drugs at the pharmacy counter or may pay higher than required out-of-pocket costs. Among Medicare beneficiaries who subsequently become eligible for Medicaid, Medicare-only beneficiaries not previously enrolled in a PDP are likely to experience more difficulties compared with those who had enrolled in a PDP prior to becoming eligible for Medicaid. Because the information systems used are not real-time processing systems, the enrollment process takes place over a period of about 2 months.

Given the time involved in processing beneficiary data under current procedures, pharmacies may not have up-to-date PDP enrollment information on new dual-eligible individuals. This may result in beneficiaries having difficulty obtaining medications at the pharmacy. To illustrate why this occurs, we present the hypothetical example of Mr. Smith, who, as a Medicare beneficiary did not sign up for the Part D drug benefit and, therefore, upon becoming Medicaid-eligible, must be enrolled in a PDP. (Fig. 2 shows the steps in Mr. Smith's enrollment process.)

Figure 2: Mr. Smith, a Hypothetical Example of the Enrollment Process for a Newly Identified Dual-Eligible Beneficiary Who Was Medicare-Eligible but without Previous Part D Coverage



Source: GAO.

NOTE: The dates presented in this example of enrollment for Mr. Smith generally represent the best-case scenario. The range of dates represent the minimum and maximum length of elapsed time allowed for processing and notification, based on information provided by CMS. GAO makes no assurances that the events described would occur on the dates provided for any specific dual-eligible beneficiary.

^aThe scenario presented reflects an application to Medicaid based on a reason other than disability. State Medicaid agencies have 45 days to make eligibility determinations not based on disability and 90 days for eligibility determinations based on disability, subject to extensions in certain circumstances.

^bIf the state Medicaid agency did not determine that Mr. Smith was eligible for Medicaid before it submitted its September dual-eligible file, his information could not be submitted until October. This scenario is not presented in this figure.

From the time Mr. Smith applies for his state's Medicaid program on August 11, it takes about 1 month for him to receive notification from the state that he is eligible for Medicaid. It takes until October 15 before the PDP notifies Mr. Smith of his enrollment and until October 16 before all the necessary information is available to his pharmacy. If Mr. Smith had sought to obtain prescription drugs prior to October 16, the pharmacy would have had difficulty getting the PDP billing information needed to process claims on his behalf.³⁹

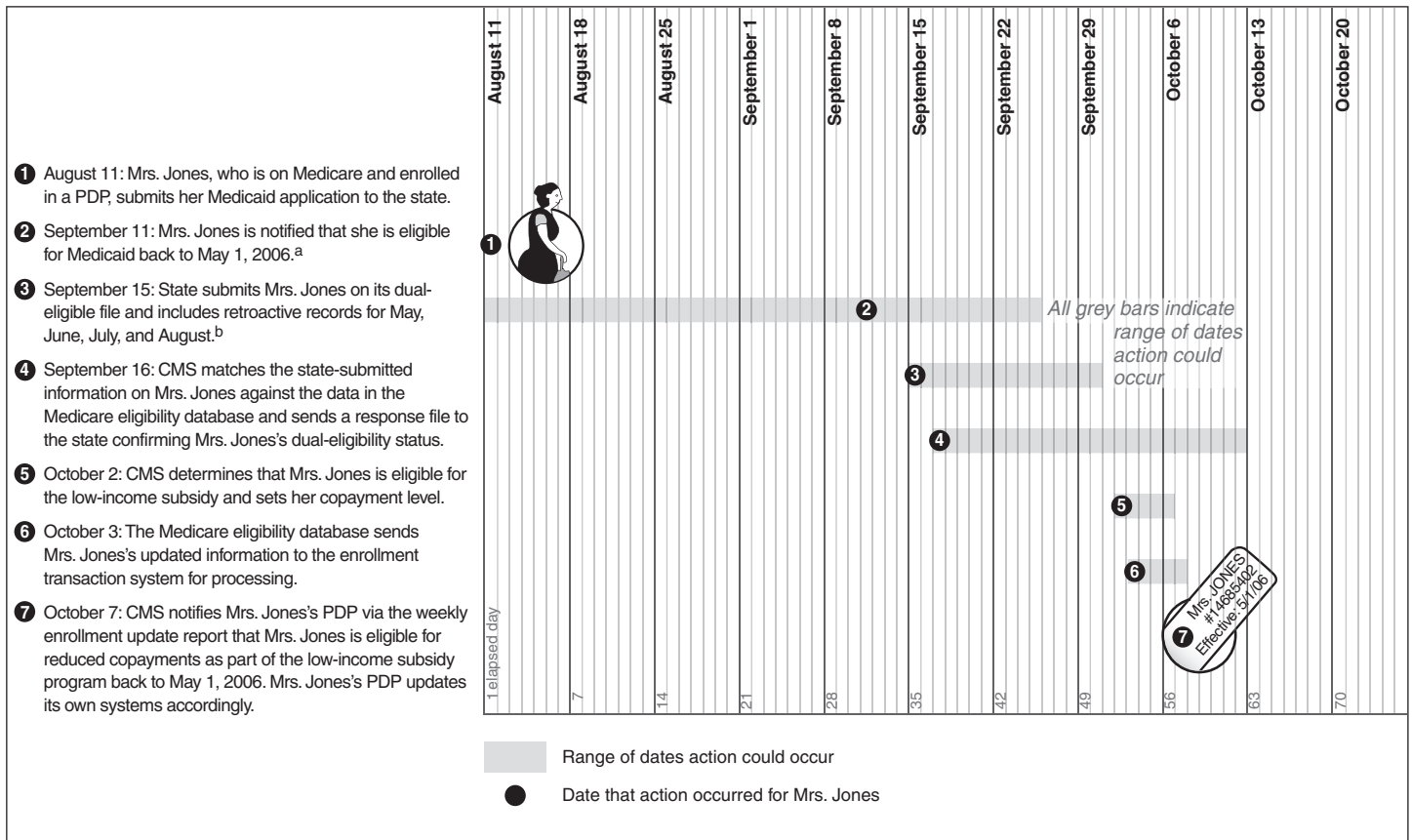
The reason this gap occurs is that some of the enrollment and PDP assignment processing steps are done at scheduled intervals, such as once a month or once a week. According to CMS, because of the challenges some state Medicaid agencies have in compiling the dual-eligible file, CMS requires the file be submitted just once a month. CMS waits until it receives the monthly dual-eligible files from all state Medicaid agencies before determining each individual beneficiary's subsidy level and making the PDP assignment for these beneficiaries. State Medicaid agencies that submit their dual-eligible file to CMS early in the monthly cycle do not have their beneficiaries' subsidy levels determined or the assignments to a PDP made any sooner than the last state to submit its file. Deeming and PDP assignment can take up to 10 days. Similarly, CMS's system of notifying the PDP of a beneficiary assignment is on a weekly cycle, beginning on Saturday. Thus, regardless of what day in the week CMS's enrollment transaction system receives a beneficiary's PDP assignment and processes that enrollment, the information is not communicated to the PDP until the following Saturday. It takes up to another week before the beneficiary receives a membership card or other membership documentation from the PDP or the pharmacy has computerized access to the Part D information needed to properly process a claim if an eligibility query is used to obtain billing information. Thus, the time elapsed from the date the state notified Mr. Smith of his eligibility for Medicaid to the date

³⁹The pharmacy would be able to fill Mr. Smith's prescription and bill a PDP serving as a contingency option if Mr. Smith produced evidence of entitlement to both Medicare and Medicaid at the pharmacy.

Mr. Smith was notified by his assigned PDP of his Part D enrollment was at least 35 days.

Other new dual-eligible beneficiaries may incur out-of-pocket costs at the pharmacy that are too high for their dually eligible status because of the time it takes information on the beneficiary's new status to reach their PDP. To illustrate this case, we present the hypothetical example of Mrs. Jones, a Medicare beneficiary who becomes eligible for Medicaid but had already enrolled in a PDP. (See fig. 3.) When Mrs. Jones, who also applied for Medicaid on August 11, goes to the pharmacy on September 12, the pharmacy charges Mrs. Jones the same copayments that she was charged as a Medicare-only Part D beneficiary instead of the reduced amount for dual-eligible beneficiaries. This occurs because the PDP, and consequently the pharmacy, does not have up-to-date information on Mrs. Jones's status as a dual-eligible beneficiary; this information must go through processing steps similar to those for Mr. Smith. That is, the state Medicaid agency must first submit Mrs. Jones's name to CMS on its dual-eligible file, which is done monthly. Subsequently, CMS must determine Mrs. Jones's level of subsidy according to the agency's schedule for the deeming process. Mrs. Jones's PDP will change her copayment information only after it receives CMS's weekly notification of enrollment transactions on October 7.

Figure 3: Mrs. Jones, a Hypothetical Example of the Enrollment Process for a Newly Identified Dual-Eligible Beneficiary Who Was Medicare-Eligible and Had Previous Part D Coverage



Source: GAO.

Note: The dates presented in this example of enrollment for Mrs. Jones generally represent the best-case scenario. The range of dates represents the minimum and maximum length of elapsed time allowed for processing and notification, based on information provided by CMS. GAO makes no assurances that the events described would occur on the dates provided for any specific dual-eligible beneficiary.

^aThe scenario presented reflects an application to Medicaid based on a reason other than disability. State Medicaid agencies have 45 days to make eligibility determinations not based on disability and 90 days for eligibility determinations based on disability, subject to extensions in certain circumstances.

^bIf the state Medicaid agency did not determine that Mrs. Jones was eligible for Medicaid before it submitted its September dual-eligible file, her information could not be submitted until October. This scenario is not presented in this figure.

Any dual-eligible beneficiary who has a change in subsidy status, such as dual-eligible beneficiaries who enter a nursing home, may temporarily face higher than required out-of-pocket costs for drugs due to processing

delays. Residents of nursing homes who are dual-eligible beneficiaries are not required to pay any copayments, but they could be charged until the PDP updates its own data based on information provided by CMS. Recognizing the time lags that pharmacies encounter in receiving complete Part D information on dual-eligible beneficiaries, CMS issued a memorandum in May 2006 requiring PDP sponsors to use the best available data to adjust a beneficiary's copayment, meaning that PDPs need not wait for CMS to notify them of a status change but can make adjustments based on notification received from a nursing facility or state agency. However, according to some we spoke with, PDPs vary in terms of their willingness to act on information provided by a party other than CMS.⁴⁰

The time intervals associated with the Part D enrollment process for new dual-eligible beneficiaries can lengthen when data entry errors occur or when a dual-eligible beneficiary is identified by the state after the state has submitted its monthly dual-eligible file. For example, if CMS cannot match information from its Medicare eligibility database with a beneficiary's information listed in the state's dual-eligible file, the state must find the source of the problem and resubmit the beneficiary's information in the following month's dual-eligible file. State Medicaid agency officials told us that generally mismatches occurred in 2006 because of errors in a birth date or Social Security number. CMS reported that for the month of June 2006, about 17,000 to 18,000 names in state Medicaid agencies' dual-eligible files could not be matched against information in the Medicare eligibility database. This number of mismatches is down from 26,000 mismatches earlier in the program.

Tools Designed to Help Pharmacies Have Not Worked Well

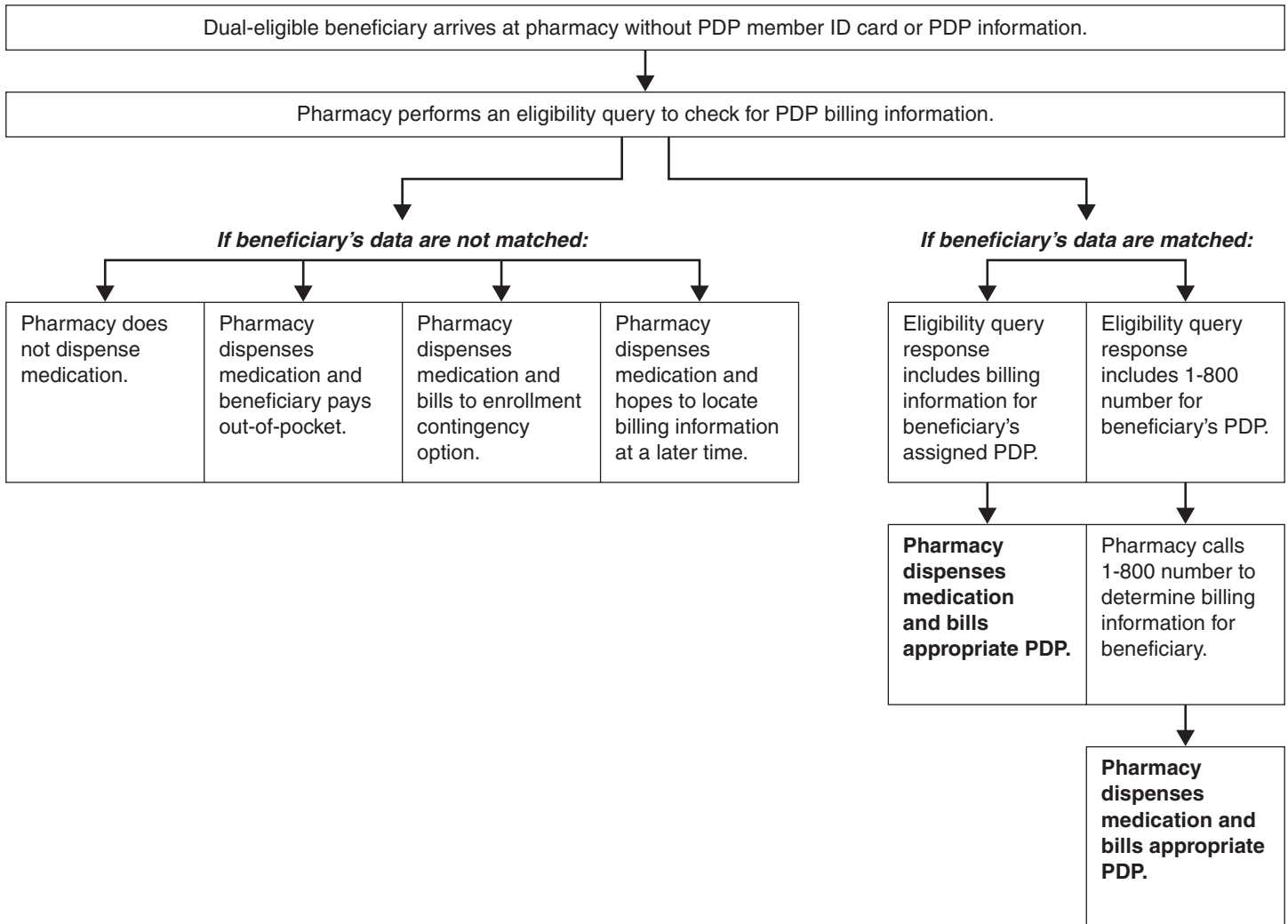
CMS has provided pharmacies with certain tools to help process a claim when a beneficiary does not present adequate billing information or has not been enrolled in a PDP. The eligibility query was designed to provide billing information to pharmacies when dual-eligible beneficiaries do not have their PDP information, but pharmacies report problems using the tool. The enrollment contingency option was designed to ensure that dual-eligible beneficiaries who were not yet enrolled in a PDP could get their medications, while also providing assurance that the pharmacy would be

⁴⁰In commenting on a draft of this report, CMS officials noted that they updated this guidance to PDPs in December 2006.

reimbursed for those medications. Problems with reimbursements have led some pharmacies to stop using the enrollment contingency option.

The eligibility query was developed by CMS to help pharmacies determine which plan to bill when a dual-eligible beneficiary lacks proof of enrollment, but about half of the time the query system returns a response indicating a match was not found (see fig. 4). To obtain billing information on individuals without a PDP membership card or other proof of Part D enrollment, pharmacies have modified their existing computer systems to allow them to query CMS's Medicare eligibility database. Using the Part D eligibility query, pharmacies can enter certain data elements—such as an individual's Social Security number, Medicare ID number, name, and date of birth—to verify whether the individual is a dual-eligible beneficiary and whether the individual has been assigned to a PDP. Ideally, when a match occurs, the pharmacy receives an automated response within seconds showing codes that contain the standard billing information necessary to file a claim—such as the identity of the PDP sponsor and the member ID number. According to CMS, of all the eligibility queries pharmacies initiated in September 2006, about 55 percent enabled them to match data identification elements with an individual in the Medicare eligibility database. In comments on a draft of this report, the agency explained that pharmacies had used the eligibility query for nonenrolled individuals whose data would not otherwise be in the system.

Figure 4: Steps Pharmacies Take When a Dual-Eligible Beneficiary Lacks Evidence of PDP Membership



Source: GAO.

In cases where the PDP has not yet submitted standard billing information to CMS, the pharmacy must spend additional time contacting the PDP. In cases where the dual-eligible beneficiary has been assigned to a PDP, but the PDP has yet to submit the standard billing information, the eligibility query response contains only a 1-800 phone number for the assigned PDP. In these cases, pharmacies must spend additional time contacting the 1-800 number to obtain needed billing information. In April 2006, about

13 percent of the eligibility query responses that matched a beneficiary did not contain the standard billing information.

Pharmacy association representatives and individual pharmacists we met with told us that improvements to the eligibility query were needed. They said the eligibility query would be more useful if the responses pharmacies receive contained such information as the name of the PDP in which the beneficiary is enrolled, the effective date of the beneficiary's enrollment in the PDP, and the beneficiary's low-income subsidy status, rather than just a 1-800 number or the standard billing information that is now provided. They also noted that the frequency with which the eligibility query responds without the standard billing information is also problematic; without adequate billing information the pharmacy has to make a telephone call to obtain the appropriate billing information.

In cases where the eligibility query does not produce a match but the pharmacy has other evidence that the individual is dually eligible for Medicare and Medicaid, such as ID cards or a letter from the state, CMS has provided pharmacies with an enrollment contingency option. That is, the pharmacies can submit their claims to a nationwide PDP sponsor—WellPoint—which CMS has contracted with to provide pharmacies with a source of payment for prescriptions filled for dual-eligible beneficiaries who have yet to be enrolled in a PDP. The WellPoint enrollment contingency option was intended for use in cases where the pharmacy can confirm that an individual is dually eligible for Medicare and Medicaid but cannot determine the beneficiary's assigned PDP through the eligibility query. In such cases, claims are screened for eligibility, and if the beneficiary is indeed dually eligible, but has not yet been enrolled in a PDP, the beneficiary gets enrolled in a PDP offered by WellPoint.

The WellPoint enrollment contingency option has often not functioned as intended. For example, WellPoint was billed for a number of claims where the beneficiary was enrolled in another PDP. As of November 26, 2006, 46.0 percent of the 351,538 Medicare ID numbers with claims that were billed to WellPoint had already been assigned to a PDP. CMS and WellPoint officials told us WellPoint reconciles payment for these claims directly with the beneficiary's assigned PDP. However, pharmacy association representatives told us that, in some cases, WellPoint required the pharmacies to refund payments for these claims to WellPoint and then

submit the claim to the appropriate PDP.⁴¹ In other cases, pharmacies bill WellPoint without supplying the necessary beneficiary data elements. For instance, rather than entering the individual's actual Medicare ID number, the pharmacy may enter dummy information into the Medicare ID field. As of November 26, 2006, CMS reported that, roughly 35 percent of the Medicare ID numbers submitted to WellPoint were invalid, requiring pharmacies to refund their outlays on claims using these numbers. In addition, about 4 percent of the Medicare ID numbers were valid but the individual was either not eligible for Medicaid or was not eligible for Part D enrollment (for instance due to incarceration). WellPoint required pharmacies to refund money for these claims as well. According to one state pharmacy association representative, some pharmacies in the state have discontinued using the WellPoint contingency option because of the reimbursement difficulties. Only about 15 percent of Medicare ID numbers with claims filed through the WellPoint option were associated with individuals eligible for enrollment in the WellPoint PDP.

Pharmacy association representatives noted that some pharmacies dispense medications to individuals without proof of Part D enrollment, hoping to get needed billing information at a later date that will allow them to properly submit a claim. One state pharmacy association representative noted that pharmacies serving only long-term care facilities dispense medication without assurance of reimbursement because they are required to do so under the contractual arrangements they have with the long-term care facilities.

Pharmacy association representatives told us that after-the-fact reimbursement of drug claims is problematic. According to the pharmacy association representatives, it can be burdensome for staff to determine where to appropriately resubmit the claim. They also noted that PDPs will sometimes reject retroactive claims that are submitted after a certain period of time has elapsed.

⁴¹In commenting on a draft of this report, CMS indicated that once it implemented plan-to-plan reconciliation in early 2006, WellPoint reconciled claims for beneficiaries already enrolled in another PDP with the appropriate PDP.

Medicare Pays PDPs to Provide Retroactive Coverage but Beneficiaries Have Not Been Informed of Their Right to Reimbursement

With the current combination of policies and requirements under which CMS operates, Medicare pays PDPs to provide retroactive coverage to Medicare beneficiaries newly eligible for Medicaid. However, until March 2007, CMS did not inform these beneficiaries of their right to seek reimbursement for costs incurred during the retroactive period that can last several months. Given the vulnerability of the dual-eligible beneficiary population, it seems unlikely that the majority of these beneficiaries would have contacted their PDP for reimbursement if they were not notified of their right to do so. GAO found that Medicare paid PDPs millions of dollars in 2006 for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs.

Retroactive coverage for dual-eligible beneficiaries stems from both CMS's Part D policy and from Medicaid requirements. Under the MMA, once an individual who is not enrolled in a plan qualifies as a dual-eligible beneficiary, CMS is required to enroll the individual in a PDP.⁴² However, the MMA does not precisely define when Part D coverage for these beneficiaries must become effective.⁴³ As initially written, when enrolling a Medicare beneficiary without Part D coverage who became eligible for Medicaid, CMS's policy set the effective coverage date prospectively as the first day of the second month after CMS identified the individual as both Medicare and Medicaid eligible.⁴⁴ In March 2006, CMS changed this policy, making coverage retroactive to the first day of the month of Medicaid eligibility. In making this change, CMS cited concerns about enrollees experiencing a gap in coverage under its prior enrollment policy. Federal Medicaid law requires that a Medicaid beneficiary's eligibility be set retroactively up to 3 months prior to the date of the individual's application if the individual met the program requirements during that

⁴²Social Security Act § 1860D-1(b)(1)(C).

⁴³Federal regulations also do not clearly define the effective date of coverage for dual-eligible beneficiaries and instead only require individuals who are Part D eligible and subsequently become eligible for Medicaid to be enrolled in a PDP by CMS as soon as practicable in a process to be determined by CMS. See 42 C.F.R. § 423.34(f)(3).

⁴⁴However, in response to a draft of this report, CMS officials notified us that, beginning with those dual-eligible beneficiaries identified by states in February 2006, coverage for dual-eligible beneficiaries was effective January 1, 2006, or the effective date of Medicaid coverage, whichever was later.

time.⁴⁵ Therefore, for this group of dual-eligible beneficiaries, Part D coverage may extend retroactively for several months prior to the actual date of PDP enrollment by CMS.

The mechanics and time frames for Part D retroactive coverage can be illustrated by the hypothetical case of Mr. Smith, a Medicare beneficiary who was not enrolled in a PDP when he applied for Medicaid. On September 11, Mr. Smith's state Medicaid agency made him eligible for Medicaid benefits as of May 11, 3 months prior to his August 11 program application, as he met Medicaid eligibility requirements during that retroactive period. In October, CMS notified Mr. Smith of his enrollment in a PDP and indicated that his Part D coverage was effective retroactively as of May 1, the first day of the month in which he became eligible for Medicaid.

Medicare's payment to Mr. Smith's PDP, beginning with his retroactive coverage period, consists of three major components, two of which are fixed and a third that varies with Mr. Smith's cost-sharing obligations.

- The first component is a monthly direct subsidy payment CMS makes to Mr. Smith's PDP toward the cost of providing the drug benefit.
- The second component is the monthly payment CMS makes to Mr. Smith's PDP to cover his low-income benchmark premium.
- The third component covers nearly all of Mr. Smith's cost-sharing responsibilities, such as any deductibles or copayments that he would pay if he were not a dual-eligible beneficiary. CMS makes these cost-sharing payments to his PDP based on the PDP's estimate of the typical monthly cost-sharing paid by beneficiaries. CMS later reconciles Mr. Smith's cost-sharing payments with the PDP based on his actual drug utilization as reported by the PDP to CMS.⁴⁶

⁴⁵Social Security Act §1902(a)(34) (codified, as amended, at 42 U.S.C. §1396a(a)(34)). Under section 1115 of the Social Security Act, the Secretary of Health and Human Services may waive this requirement for demonstration projects that are likely to assist in promoting the objectives of the Medicaid program. Social Security Act §1115 (codified, as amended, at 42 U.S.C. §1315). If a state receives approval of such a waiver, the state only needs to extend Medicaid eligibility back to the date of application for the population covered under the demonstration.

⁴⁶For the 2006 benefit year, CMS is requiring PDP sponsors to submit all utilization information by the end of May 2007 and will begin the reconciliation process in August 2007.

Under CMS's retroactive coverage policy, Mr. Smith's PDP receives all three components of payments for the months of May, June, July, August, and September, although Mr. Smith was not enrolled in the PDP until October. Medicare pays Mr. Smith's PDP sponsor about \$60 a month for the direct subsidy and another monthly payment for the low-income premium up to the low-income benchmark, which ranges from \$23 to \$36 depending on Mr. Smith's location.⁴⁷ We estimate that for all dual-eligible beneficiaries enrolled by CMS with retroactive coverage, Medicare paid PDPs about \$100 million in 2006 for these two monthly payment components for the retroactive period.⁴⁸ Unlike the cost-sharing component of Medicare's payments, the two monthly payment components are not subject to a reconciliation process tied to utilization of the benefit.⁴⁹ This means that if Mr. Smith's PDP did not reimburse Mr. Smith for any prescription drugs purchased during the retroactive coverage period, the PDP would have to refund Medicare the cost-sharing payment, but would keep the direct subsidy payments and the low-income premium payments.⁵⁰

⁴⁷In 2006, the direct subsidy payment was \$60.10 (subject to adjustment based on the beneficiary's health) and \$53.08 for 2007. The low-income benchmark is a regional amount that ranged from \$23.25 to \$36.39 in 2006 and ranges from \$20.56 to \$33.56 in 2007.

⁴⁸This total represents only Medicare payments to PDPs associated with the retroactive coverage policy for beneficiaries enrolled by CMS after becoming dually eligible. Based on data provided by CMS, we estimated that roughly 256,000 dual-eligible beneficiaries enrolled by CMS from April through December 2006 were provided retroactive coverage. We assumed that most of these beneficiaries were provided up to 5 months of retroactive coverage from the date they were notified of their PDP enrollment—a period that includes both their retroactive Medicaid coverage and PDP enrollment processing time. We estimated that, for each month, PDP sponsors received approximately \$90 per beneficiary in direct subsidy and low-income premium payments.

⁴⁹CMS conducts a separate reconciliation for all payments made to PDPs, termed risk sharing, in which CMS may recoup a share of Medicare payments made to a Part D sponsor that exceed the sponsor's actual costs. Recoupment may occur if actual costs are less than the sponsor's estimates of revenue necessary to provide Part D benefits to all its enrollees. CMS performs risk sharing with Part D sponsors at the end of each coverage year.

⁵⁰As consistent with federal requirements, Medicare pays PDPs the same monthly premium amounts for periods of retrospective coverage as for prospective coverage, although evidence suggests that beneficiaries' drug purchases are likely to be significantly lower during the retrospective periods. On average, beneficiaries without drug insurance use 25 percent fewer prescriptions and spend 40 percent less on drugs than do insured beneficiaries. See John Poisal and George Chulis, "Medicare Beneficiaries and Drug Coverage," *Health Affairs*, vol. 19, no. 2, March/April 2000, pp. 248-256.

Medicare makes the direct subsidy and low-income premium payments for the retroactive coverage period because CMS requires PDP sponsors to reimburse beneficiaries for covered drug costs incurred during this period. However, we found that CMS did not inform dual-eligible beneficiaries about their right to seek reimbursement or instruct PDP sponsors on what procedures to use for reimbursing beneficiaries or others that paid on the beneficiary's behalf for drugs purchased during retroactive periods. The model letters that CMS and PDPs used until March 2007 to notify dual-eligible beneficiaries of their PDP enrollment did not include any language concerning reimbursement of out-of-pocket costs incurred during retroactive coverage periods.⁵¹ After reviewing a draft of this report and our recommendations, CMS modified the model letters that the agency and PDPs use to notify dual-eligible beneficiaries about their PDP enrollment. The revised letters let beneficiaries know that they may be eligible for reimbursement of some prescription costs incurred during retroactive coverage periods.

Given the vulnerability of the dual-eligible beneficiary population, it seems unlikely that the majority of these beneficiaries would have contacted their PDP for reimbursement if they were not notified of their right to do so nor would they likely have retained proof of their drug expenditures.⁵² In the case of Mr. Smith, for example, he would need receipts for any drug purchases made during the retroactive period—about 5 months preceding the date he was notified of his PDP enrollment—at a time when he could

⁵¹In commenting on a draft of this report, CMS noted that it had educated its partners—organizations that assist Medicare beneficiaries with enrollment—about this policy, so that they could help dual-eligible beneficiaries understand their right to reimbursement for retroactive drug costs. The agency pointed to an April 2006 fact sheet for partners on how Medicare beneficiaries, in general, should seek repayment of out-of-pocket costs incurred while their plan enrollment was being processed. However, the guidance did not make specific reference to the rights of dual-eligible beneficiaries who are provided several additional months of retroactive coverage nor did it define which drug costs are covered.

⁵²PDPs must also reimburse beneficiaries in cases such as Mrs. Jones—a Medicare beneficiary previously enrolled in a PDP who subsequently became eligible for Medicaid, and thus the low-income subsidy (see fig. 3). CMS would make the payments for the low-income benchmark premium to the PDP retroactive to the date Mrs. Jones had a change in subsidy status and the PDP would reimburse Mrs. Jones for that period up to the same premium amount. For the cost-sharing payment, the PDP has the prescription drug claims for the retroactive period, which include the amount Mrs. Jones paid at the pharmacy. The PDP would resolve differences between the amount she actually paid and the amount she would have paid given the low-income subsidy. If the PDP has automated systems to amend claims and pay accordingly, Mrs. Jones would not have to contact the PDP to be refunded for her costs.

not foresee the need for doing so. Finally, Mr. Smith or someone helping him would have to find out how and where to claim reimbursement from his PDP. Under CMS's 2006 policy, even if Mr. Smith had submitted proof of his drug purchases, he would not be eligible for reimbursement if CMS had enrolled him in a PDP that did not cover his prescriptions or did not have Mr. Smith's pharmacy in its network.⁵³ Nevertheless, Mr. Smith's PDP would have received monthly direct subsidy and low-income premium payments for Mr. Smith for the retroactive coverage period.

For 2006, CMS did not calculate aggregate payments made to PDP sponsors for retroactive coverage. Further, the agency did not monitor reimbursements to dual-eligible beneficiaries for drug purchases made during the retroactive period. Agency officials told us that they have data to determine the PDP payments and beneficiary reimbursements. As a result of not tracking this information, CMS does not know how much of the roughly \$100 million in direct subsidy and low-income premium payments for retroactive coverage in 2006 was used by PDPs to pay for drug expenses claimed by dual-eligible beneficiaries for drugs purchased during retroactive coverage periods.

CMS Has Taken Actions to Address Challenges Faced by New Dual-Eligible Beneficiaries and Pharmacies

Given the experience of early 2006, CMS has taken several actions to improve the transition of dual-eligible beneficiaries to Part D. First, the agency has taken steps to facilitate the change in drug coverage for Medicaid beneficiaries whose date of Medicare eligibility can be predicted—about one-third of new dual-eligible beneficiaries enrolled by CMS. In August 2006, CMS implemented a new prospective enrollment process that state Medicaid agencies may use to eliminate breaks in prescription drug coverage for these beneficiaries. Second, CMS is taking steps to improve tools pharmacies use when dual-eligible beneficiaries seek to fill a prescription, but do not have their PDP enrollment information. Third, CMS has plans to integrate the agency's information

⁵³Under CMS's 2006 policy, PDP sponsors were responsible for compensating dual-eligible beneficiaries, or those that paid on their behalf, for out-of-pocket costs incurred during the retroactive period for drugs covered by the PDP. Similarly, if a pharmacy provided medications to Mr. Smith without charge during this time period, the PDP sponsor would also be required to reimburse the pharmacy for covered drug costs if the pharmacy was in the PDP's network. Under CMS's 2007 policy, the agency requires that PDP sponsors reimburse third-party payers for allowable drug charges during a retroactive eligibility period of up to 7 months, including charges for nonformulary drugs or formulary drugs with prior authorization requirements.

systems to increase the efficiency of the systems involved in the enrollment process.

CMS Instituted Prospective Enrollment to Help Ease Challenges of Certain New Dual-Eligible Beneficiaries

CMS implemented a new prospective enrollment process in August 2006 to help Medicaid beneficiaries who become Medicare eligible transition to Part D without a break in coverage. Under the prospective enrollment process, state Medicaid agencies voluntarily can include on the monthly state dual-eligible file those Medicaid beneficiaries predicted to become Medicare eligible, for instance Medicaid beneficiaries who are nearing their 65th birthday. Two months prior to the date the beneficiary will become Medicare eligible, CMS assigns the beneficiary to a PDP. By completing the assignment process prior to when these beneficiaries become Medicare eligible, CMS officials told us that these beneficiaries should have all their PDP enrollment information when their Medicare Part D coverage begins.

Prior to the prospective enrollment process, Medicaid beneficiaries who became Medicare eligible experienced a gap of up to 2 months during which they were no longer eligible for Medicaid prescription drug coverage but had yet to receive information on their Medicare Part D drug coverage. This is because state Medicaid agencies were allowed to include in the monthly state dual-eligible file only those dual-eligible beneficiaries who were known to be eligible for Medicaid and Medicare at the time the file was sent. State Medicaid agencies were required to end Medicaid coverage for prescription drugs when the beneficiary became Part D eligible.

Because prospective enrollment was in its very early stages during our audit work, we cannot evaluate how effectively the new process is working to mitigate the gaps in coverage some new dual-eligible beneficiaries faced. In the first month of implementation, 38 state Medicaid agencies submitted records identifying at least some prospective dual-eligible beneficiaries. CMS officials attributed the lack of submission of the names of prospective dual-eligible beneficiaries by some state Medicaid agencies in August 2006 to the short time frame state Medicaid agencies were given to change how they compiled the dual-eligible file. As of November 2006, the state Medicaid agencies for all 50 states and the District of Columbia have included prospective dual-eligible beneficiaries in their monthly file. While it is too early to gauge the impact of the process on beneficiaries, we believe that prospective enrollment has the potential to provide continuous coverage for those beneficiaries who can be predicted to become dually eligible. State Medicaid officials also told us

that prospective enrollment is a beneficial change to the process of identifying and enrolling new dual-eligible beneficiaries.

CMS Working to Improve Utility of Eligibility Query and Billing Contingency Option

CMS is taking steps to improve the eligibility query and the billing contingency option. CMS worked with the pharmacy industry to change the format of the eligibility query to include more complete information. Also, CMS officials said they planned to make changes to the enrollment contingency contract to institute a preliminary screen of Medicare eligibility and Part D plan enrollment before a claim goes through the system.

In response to requests from pharmacies that more information be provided through the eligibility query, CMS officials told us that agency staff worked with the National Council for Prescription Drug Programs, Inc.—a nonprofit organization that develops standard formats for data transfers to and from pharmacies—to change the format of the eligibility query and increase the amount of information pharmacies could get from the responses. As part of the planned improvements, eligibility query responses for beneficiaries identified in the database will include—in addition to the data elements previously included—the beneficiary’s name and birth date, the PDP’s identification number, and the beneficiary’s low-income subsidy status. The new specifications for the eligibility query were released December 1, 2006. Pharmacies have to work with their own software vendors to implement the changes to their own systems.

CMS is also taking steps to improve the availability of the information pharmacies access through the eligibility query. CMS officials told us that, after being notified of a confirmed enrollment by CMS via a weekly enrollment update, PDPs should submit standard billing information to CMS within 72 hours. However, sometimes PDPs hold the information for longer than 72 hours. According to CMS, the time it takes PDPs to submit billing information to the agency has improved since the beginning of the Part D program. While CMS does not monitor the amount of time it takes for PDPs to submit billing information, the agency has begun monitoring Medicare’s eligibility database to identify PDPs that have a large number of enrollees for whom billing information is missing. As part of this effort, CMS sends a file monthly to each PDP that lists enrollees without billing information. CMS guidance to PDPs states that each PDP should successfully submit standard billing information for 95 percent of the PDP’s enrollees each month. According to CMS data, as of October 1, 2006, about 27 percent of PDPs with CMS-assigned, dual-eligible beneficiaries had billing information for less than 95 percent of their CMS-assigned,

dual-eligible beneficiaries. Of those that did not meet the 95 percent threshold, most had fewer than 20 CMS-assigned, dual-eligible beneficiaries.

CMS has implemented certain changes for 2007 to address the large number of problematic claims going through the WellPoint enrollment contingency option. It has directed WellPoint to check an individual's Medicare eligibility and Part D enrollment before the claim is approved, using a new daily update report from Medicare's eligibility database. This is expected to allow WellPoint to deny claims at the point-of-sale that should not be paid through this option, thereby reducing the number of claims that must be reconciled at a later date.

CMS Is Attempting to Address Information Systems Issues, but without Adequate Testing, Problems May Continue

CMS is now making changes to improve the efficiency of key information systems involved in the enrollment process. It is redesigning and integrating these information systems to reduce redundancies and to synchronize data currently stored in different systems, which should lead to a more efficient enrollment process. While CMS is performing unit, system, and integration testing on these changes, it has no definitive plans to perform end-to-end testing on the changes to the overall information systems infrastructure.⁵⁴ CMS is pursuing contractual help to determine the extent of testing that it can perform in the future.

CMS is currently integrating information from the Medicare eligibility database with information from the enrollment transaction system because duplicative demographic and other data are stored in both systems. According to CMS information technology (IT) officials, because these data are not stored in one place and a huge amount of enrollment traffic is moving back and forth between these two systems, it has been a very large burden for the agency to synchronize and maintain a single set of data. CMS IT officials told us that they spent the first 6 months of Part D implementation stabilizing the supporting information systems and have only now begun to look at efficiencies that can be achieved through

⁵⁴In unit testing, each module is tested alone in an attempt to discover any errors in its code. System testing is performed to discover defects that are properties of the entire system rather than of its individual components. Integration testing is performed to verify that multiple applications that work together to accomplish a system function, when combined, work correctly. Because the separate applications being integrated have already been tested successfully, integration testing focuses on ensuring that the interfaces work correctly and that the integrated software meets specified requirements.

integration and mergers that can reduce maintenance and processing times. In the long term, the agency hopes to integrate all beneficiary, entitlement, and enrollment information into one database.

CMS IT officials contend that true end-to-end testing of these current changes may not be feasible given the agency's limited time and resources and the number of scenarios that would have to be tested in the more than 600 different PDPs. In addition, true end-to-end testing would involve thorough interface testing with SSA, and state Medicaid agency and PDP systems, which are not standardized and vary widely. While we agree that end-to-end testing will be difficult given the multiple partners involved and the complexity of the program's systems infrastructure, it is crucial to mitigate the risks inherent in CMS's planned changes. End-to-end testing is a highly recognized systems development best practice and is considered essential to ensure that a defined set of interrelated systems, which collectively support an organizational core business area or function, interoperate as intended in an operational environment. These interrelated systems include not only those owned and managed by the organization, but also the external systems with which they interface. Because end-to-end testing can involve multiple systems and numerous partner interfaces, it is typically approached in a prioritized fashion taking into consideration resources, test environments, and the willingness of external parties to participate. CMS IT officials acknowledge that there are risks associated with implementing these changes but still do not plan to conduct end-to-end testing even on a limited basis.

CMS Randomly Assigns Dual-Eligible Beneficiaries to PDPs; Some States Assigned Individuals Using a More Tailored Approach

As required under the MMA and implementing regulations, for dual-eligible beneficiaries who have not enrolled in a Part D plan, CMS makes random assignments to PDPs based only on the premium amount and the geographic location of the PDP. This method ensures that PDP sponsors enroll an approximately equal number of beneficiaries. However, state Medicaid officials and others assert that dual-eligible beneficiaries assigned to PDPs by CMS are often enrolled in PDPs that do not meet their drug needs. For the initial PDP assignments for January 2006, some SPAPs used additional criteria—including drugs used by beneficiaries—to enroll or reassign beneficiaries to PDPs that were more appropriate to their individual circumstances. SPAP officials reported that these alternative methods produced beneficial results. However, CMS and PDP sponsors pointed out that random assignment works to enroll beneficiaries into PDPs, and that there is no need to use additional criteria.

When Enrolling Dual-Eligible Beneficiaries, CMS Considers PDP Premiums and Geographic Location

CMS assists in the enrollment of dual-eligible beneficiaries who have not enrolled in a Part D plan on their own by randomly assigning them in approximately equal numbers among eligible PDP sponsors in each region. Under the MMA, the agency may only consider the premiums of the PDPs in the region when making these assignments.⁵⁵ CMS first distributes beneficiaries randomly among those PDP sponsors that offer one or more PDPs at or below the low-income benchmark—the average premium in a region—if there is more than one eligible PDP serving the beneficiary’s geographic location. It then assigns the beneficiaries randomly among all eligible PDPs offered by each PDP sponsor. Following the first round of enrollments, CMS has assigned new dual-eligible beneficiaries to PDPs monthly.

Dual-eligible beneficiaries may change PDPs at any time during the enrollment year.⁵⁶ When dual-eligible beneficiaries change PDPs, coverage under the new PDP becomes effective the following month. As of November 2006, 29.8 percent—1,703,018—of dual-eligible beneficiaries initially enrolled by CMS subsequently made a PDP election of their own choosing.

During the original assignments for 2006, CMS assigned some dual-eligible beneficiaries to PDPs that did not serve the area where they lived. This occurred for about 107,000 dual-eligible beneficiaries, 1.9 percent of the population randomly assigned to PDPs at that time. In these cases, CMS made inappropriate assignments because it used address information from SSA that was out-of-date or that corresponded to the individual’s representative payee—the individual or organization who manages the beneficiary’s money on the beneficiary’s behalf—rather than to the beneficiary.⁵⁷ For example, if a beneficiary resides in Arizona and their representative payee resides in Virginia, CMS would have assigned that beneficiary to a PDP serving Virginia. CMS officials pointed out that this problem was relatively minor because most of these dual-eligible beneficiaries (about 98.1 percent of those affected) were either enrolled in

⁵⁵Social Security Act § 1860D-1(b)(1)(C).

⁵⁶Social Security Act § 1860D-1(b)(3)(D); see also 42 C.F.R. § 423.38.

⁵⁷CMS only receives one address per beneficiary, which may be that of a representative payee. A representative payee is an individual or organization that receives Social Security or SSI payments for someone who cannot manage or direct the management of his or her money. The file CMS receives from SSA contains information indicating that an individual has a representative payee.

a PDP offered by a PDP sponsor that offered coverage in the beneficiary's actual region or that had a national pharmacy network. CMS officials told us that PDP sponsors serving the remainder of these beneficiaries were instructed to provide benefits to this group in accordance with their out-of-network benefits.⁵⁸ CMS officials also told us that the fact that dual-eligible beneficiaries can switch PDPs at any time addresses the issue. PDP sponsors were still required to notify all affected beneficiaries of the out-of-area assignment. CMS instructed PDPs to notify those dual-eligible beneficiaries living in an area not served by the PDP sponsor that they would be disenrolled at some future point and must contact Medicare to enroll in an appropriate PDP.

Some States Have Assigned Individuals to PDPs Using a More Tailored Approach

Under the MMA, SPAPs may enroll Part D beneficiaries into PDPs as their authorized representatives.⁵⁹ Although CMS encouraged SPAPs to follow the same enrollment process CMS uses for dual-eligible beneficiaries, CMS has allowed certain SPAPs to use additional assignment criteria. Qualified SPAPs may use alternative assignment methods—often referred to as intelligent random assignment (IRA)—to identify PDP choices for their members that meet their individual drug needs. IRA methods consider beneficiary-specific information, such as drug utilization, customary pharmacy, and other objective criteria to narrow the number of PDP options to which a member could be assigned. With CMS approval, SPAPs may enroll members randomly among PDPs that meet these given criteria. However, SPAPs may not discriminate among PDPs by enrolling members into a specific or preferred PDP—a practice referred to as steering.⁶⁰

⁵⁸PDPs are required to cover the cost of prescriptions filled at pharmacies that are outside of the PDP's pharmacy network; however, the beneficiary may have to pay more of the cost.

⁵⁹Qualified SPAPs must attest to CMS that they meet five criteria established by CMS, including a prohibition on discriminating against any PDP when enrolling beneficiaries. SPAPs must also qualify as authorized representatives of beneficiaries under state law in order to enroll beneficiaries in PDPs. See Social Security Act §1860D-23(b); 42 C.F.R. §423.464(e)(1). As of May 17, 2006, SPAPs in 25 states had attested to their qualified status.

⁶⁰Social Security Act §1860D-23(b)(2); 42 C.F.R. § 423.464(e)(1)(ii). CMS informed us that it has coordinated enrollment processes with SPAPs, in which SPAPs have assigned dual-eligible beneficiaries to a PDP, eliminating the need for CMS to assign these individuals to a PDP.

Using Additional Criteria,
Maine Switched PDP
Assignments to Accommodate
Drugs Used by Dual-Eligible
Beneficiaries

The SPAP in Maine is one example of an organization that took steps to reassign noninstitutionalized, dual-eligible beneficiaries, with CMS approval, by aligning their drug needs with PDP formularies, ultimately reassigning nearly half of its dual-eligible population to PDPs other than those assigned by CMS. In June 2005, state legislation was enacted that authorized the inclusion of all dual-eligible beneficiaries in Maine's existing SPAP membership.⁶¹ Maine officials sought to pass this legislation in response to concerns that this population could experience coverage disruptions during the transition to Medicare Part D as implemented by CMS. They reported that, although these individuals may switch PDPs at any time, it could take months for beneficiaries to transfer to a more appropriate PDP. Thus, after CMS had randomly assigned dual-eligible beneficiaries to PDPs, Maine reassigned certain noninstitutionalized, dual-eligible beneficiaries to different PDPs prior to January 1, 2006.

The state found support for its decision to reassign dual-eligible beneficiaries in a state analysis, which indicated that CMS assignments resulted in a poor fit for many dual-eligible beneficiaries in Maine. (See table 1.) According to the analysis, CMS had assigned roughly one-third of dual-eligible beneficiaries to PDPs that covered all of their recently used drugs. However, nearly half of dual-eligible beneficiaries in the state had a match rate—the percentage of a beneficiary's medications that appeared on the CMS-assigned PDP formulary—lower than 80 percent. The analysis also showed that about one in five dual-eligible beneficiaries had match rates below 20 percent.

⁶¹Me. Rev. Stat. Ann. tit. 22, § 254-D (2006).

Table 1: Maine Analysis of the Match Rate between Dual-Eligible Beneficiaries' Drugs and Their CMS-Assigned PDP Formularies, 2005

Match rate (percentage)	Number of dual-eligible beneficiaries	Percentage of full dual-eligible beneficiaries
100	10,778	34.0
80 to 99.99	6,393	20.1
60 to 79.99	5,103	16.1
40 to 59.99	2,211	7.0
20 to 39.99	860	2.7
Less than 20	6,384	20.1
Total	31,729	100.0

Source: Maine Department of Health and Human Services.

Notes: Maine officials calculated match rates for each dual-eligible beneficiary by comparing each beneficiary's recent drug use with the formulary of the CMS-assigned plan. These match rates were generated by a computer program that used a system that scored two points if a drug was covered without prior authorization, one point if a drug was covered but required prior authorization, and no points for drugs not covered. To calculate the match rate, the program divided the total score by the potential beneficiary maximum score.

As an alternative to random assignment based on PDP premiums and location, Maine officials developed an IRA method that considered a beneficiary's drug utilization and customary pharmacy to make new PDP assignments. Officials developed a computer program that generated scores used to rank PDPs in order of best fit for each beneficiary. The program included the 10 PDPs in the state with premiums at or below the low-income benchmark that provided their formularies to the state. It compared the drugs on these PDPs' formularies to the beneficiary's drug utilization history compiled from Medicaid claims for the 3 months prior to the date of assignment (September, October, and November 2005) and assigned an aggregate score to each PDP. The scoring system differentiated between instances where a drug was on the formulary with and without prior authorization requirements.⁶² For PDPs with identical scores, the program assessed pharmacy location. If more than one PDP had the beneficiary's customary pharmacy in their network, the program randomly assigned the beneficiary among those PDPs with the highest scores. Although Maine officials conducted this analysis for all of its 2005 dual-eligible beneficiaries, after they conferred with CMS officials they reassigned only those dual-eligible beneficiaries who had lower than an 80

⁶²Prior authorization is the requirement to obtain authorization from the PDP sponsor before the PDP will cover a drug.

percent formulary match, accounting for 14,558 individuals, about 46 percent of the state's dual-eligible population.

Maine officials reported that IRA resulted in a marked improvement in match rates for beneficiaries compared to CMS's PDP assignments. For each PDP, officials calculated the match rate before and after IRA for reassigned beneficiaries. (See table 2.) This analysis showed that before the use of IRA, the weighted average match rate for all participating PDPs was 34.14 percent, and ranged from 20.59 percent to 38.64 percent across PDPs. Following the application of IRA, the weighted average match rate rose to 99.86 percent, with little variation across PDPs.

Table 2: Match Rates by PDP before and after Intelligent Random Assignment for Those Reassigned Dual-Eligible Beneficiaries

PDP	Number of dual-eligible beneficiaries reassigned using IRA	Average formulary match rate for reassigned dual-eligible beneficiaries (percentage)	
		Before reassignment	After reassignment
A	233	20.59	98.71
B	3,125	33.18	99.90
C	473	29.65	99.79
D	946	29.17	99.58
E	740	29.18	99.86
F	5,306	38.64	100.00
G	426	25.99	99.53
H	64	28.67	98.44
I	2,706	34.79	100.00
J	539	24.67	99.07
All PDPs	14,558	34.14	99.86

Source: Maine Department of Health and Human Services, GAO.

Note: To calculate the average match rate before reassignment for each PDP, Maine officials averaged the individual match rates based on the CMS-assigned PDP formulary for all dual-eligible beneficiaries the state subsequently reassigned to that PDP. To calculate the average match rate after reassignment for each PDP, Maine officials averaged the individual match rates based on the reassigned PDP formulary for all dual-eligible beneficiaries the state reassigned to that PDP. To calculate an average match rate for all plans before and after reassignment, we took a weighted average of the average match rates calculated for each plan before and after reassignment.

Maine officials noted that their continued use of IRA for dual-eligible beneficiaries is contingent on their access to key data. To make the initial assignments for dual-eligible beneficiaries effective January 1, 2006, the

New Jersey's SPAP Used Drug Utilization Data to Identify Optimal PDP Assignments Prior to CMS Enrollment

state had drug utilization information from its own Medicaid claims system. However, if the state chooses to reassign individuals again, it must obtain up-to-date utilization information. To help ensure that it would have the data needed to perform another round of IRA in the future, Maine's SPAP included in its contract with PDP sponsors a requirement to exchange with the SPAP information on pharmacy networks, formularies, and drug utilization on an ongoing basis.⁶³ For 2007, Maine reassigned 10,200, about 22 percent of dual-eligible beneficiaries, to a new PDP.

The state of New Jersey's SPAP—known as the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Program—developed and implemented an IRA method, with CMS approval, that allowed it to enroll its members in PDPs that best served their drug needs.⁶⁴ PAAD officials designed their IRA to simulate the decision process that would occur if beneficiaries had received assistance from a State Health Insurance Assistance Program⁶⁵ counselor or had used CMS's Web-based formulary finder on their own.⁶⁶

PAAD officials engaged a contractor to develop a computer program that would identify PDPs that cover each individual's prescription drug needs. The program matched information on members' maintenance drugs with formulary and pharmacy network information for all PDPs offered in New Jersey at or below the low-income benchmark.⁶⁷ The program treated married couples as one member in the assignment process to ensure that

⁶³CMS currently receives drug claims data from PDPs for the purpose of adjusting payments made to PDP sponsors. The MMA provides that these data may only be used by CMS for purposes of determining subsidies to PDPs. Social Security Act §1860D-15(d). In October 2006, CMS issued a proposed rule that would permit the agency to share claims data with other governmental and outside entities for purposes of research and evaluation of the Medicare Part D program. See Medicare Program; Medicare Part D Data, 71 *Fed. Reg.* 61445 (Oct. 18, 2006).

⁶⁴PAAD did not include any dual-eligible beneficiaries in its assignment process.

⁶⁵This program has counselors in every state and several territories who offer free individualized help with a beneficiary's Medicare questions or problems.

⁶⁶CMS developed a Web-based "Formulary Finder" that allows a user to enter the drugs they are using to find out which PDPs in an area match their drug list. This tool is available online at: <http://formularyfinder.medicare.gov/formularyfinder/selectstate.asp>

⁶⁷Maintenance drugs are used to treat medical conditions that are considered chronic, long term, and stable.

they would be enrolled in the same PDP. In all, PAAD matched 210,000 beneficiaries among six PDPs.⁶⁸

Following the application of IRA and prior to enrolling individuals, PAAD sent one of two letters to beneficiaries that explained the results of the IRA method. PAAD sent a letter to some beneficiaries indicating that one PDP best met their needs in terms of its formulary match and inclusion of their customary pharmacy. Other beneficiaries were sent letters informing them that their needs would be equally met by multiple PDPs and identified those PDPs. To satisfy CMS's requirement that the state not steer beneficiaries to a particular PDP, New Jersey included a full list of all eligible PDPs in the state on the back of the letter.

PAAD staff sent these letters in October 2005 and offered to enroll these beneficiaries if they did not receive a response by November 2005. Individuals were asked to notify PAAD of the PDP that they wanted to join and PAAD moved to enroll them in that PDP. For beneficiaries who did not respond to their letters, PAAD enrolled them into the PDP identified as the best fit by the IRA, or randomly among PDPs that equally met their needs. Of the roughly 210,000 letters sent to SPAP members, PAAD received about 130,000 letters requesting enrollment in the suggested PDP within the first month or two after PAAD sent the letters. In total, PAAD enrolled 165,207 beneficiaries, about 78.7 percent of those sent letters, into PDPs identified as the best fit by the IRA.

Stakeholders' Reactions to States' Use of Intelligent Random Assignment Protocols Are Mixed

While CMS has allowed certain SPAPs to use IRA methods to assign or reassign their members, CMS does not support the use of IRA methods to assist dual-eligible beneficiaries with Part D enrollment. CMS officials told us that any proposal to add drug utilization as a criterion for PDP assignments assumes that a beneficiary should remain on the same drugs. They contend that beneficiaries can change prescriptions to a similar drug that is on their CMS-assigned PDP's formulary and receive equivalent therapeutic value. Moreover, the officials pointed out the ability of dual-eligible beneficiaries to switch PDPs. Overall, CMS officials maintained the position that its PDP assignment method for dual-eligible beneficiaries used in fall 2005 worked well.

⁶⁸The 210,000 includes about 20,000 members of another SPAP in the state that PAAD included in the process.

In contrast, state Medicaid officials we met with generally support the use of IRA methods to assist beneficiaries in choosing a PDP that meets their individual circumstances. State Medicaid officials we met with maintained that overall, dual-eligible beneficiaries would have been in a better position during the initial transition to Medicare Part D if drug utilization information were considered in the PDP assignment process. A representative of the National Association of State Medicaid Directors (NASMD)⁶⁹ asserted that while CMS's assignment process was fair to PDP sponsors, it did not ensure that beneficiaries were enrolled in appropriate PDPs. The representative reported that CMS referred individuals who wanted to take their drug usage into account in selecting a PDP to the Medicare.gov Web site, which most dual-eligible beneficiaries are not able to use.

Some state Medicaid agencies indicated their support for IRA in the months prior to Part D implementation. At that time, 15 state Medicaid agencies made commitments to a software vendor to use a free software package designed to match beneficiaries' drug utilization history with PDP formularies as an educational tool to help them choose the PDP best aligned to their individual drug needs. However, litigation over use of the IRA software led to delays, at the end of which CMS had already assigned dual-eligible beneficiaries to PDPs. State Medicaid agencies reported that they then did not have the time to match beneficiaries, send out scorecards, and allow beneficiaries to switch PDPs before the January 1, 2006, implementation date.

Executives of PDP sponsors we spoke with stated that CMS's assignment method generally worked well; however, some executives raised concerns about IRA methodology. Two PDP sponsors raised concerns that IRA methods misinterpret formulary information. Executives from one PDP sponsor contended that there is not a need to look at drug utilization information because of the requirements for broad formularies. These executives also told us that using this method could increase the program's costs by making PDPs cover more drugs.

⁶⁹NASMD is a professional, nonprofit organization of representatives of all state Medicaid agencies (including the District of Columbia and territories).

PDP Transition Process Compliance Improved but Beneficiary Confusion Remains; 2007 Contracts More Specific

CMS actions to address problems associated with PDP implementation of pharmacy transition processes led to a more uniform application of transition processes. Pharmacy transition processes allow new PDP enrollees to obtain drugs not normally covered by their new PDP while they contact their physician about switching to a covered drug. In response to Part D sponsors' inconsistent implementation of transition drug coverage processes in early 2006, CMS issued a series of memoranda that clarified its expectations. PDP sponsors, pharmacy groups, and beneficiary advocates told us that since then, beneficiaries' ability to obtain transition drug coverage has substantially improved. However, they also report that dual-eligible beneficiaries remain unaware or confused about the significance of receiving a transition drug supply at the pharmacy and are not using the transition period to address formulary issues. CMS made the transition process requirements in its 2007 contracts with PDP sponsors more specific.

CMS Guidance on Transition Drug Coverage Improved PDP Performance

After receiving complaints that Part D enrollees experienced difficulties obtaining their medications, CMS took steps to address issues related to the availability of transition drug supplies. Federal regulations require PDP sponsors to provide for a transitional process for new enrollees who have been prescribed Part D-covered drugs not on the PDP's formulary.⁷⁰ CMS instructed PDP sponsors to submit a transition process, which would be subject to the agency's review, as part of the application to participate in Part D.

Although CMS specified its expectations for a transition process in March 2005 guidelines for Part D sponsors, the sponsors had discretion in devising their processes. The March 2005 guidelines specified that Part D sponsors should consider filling a one-time transition supply of nonformulary drugs to accommodate the immediate need of the beneficiary. The agency suggested that a temporary 30-day supply would be reasonable to enable the relevant parties to work out an appropriate therapeutic substitution or obtain a formulary exception, but it allowed Part D sponsors to decide the appropriate length of this one-time transitional supply. For residents in long-term care facilities, CMS guidance indicated that a transition period of 90 to 180 days would be

⁷⁰42 C.F.R. § 423.120(b)(3). New enrollees include beneficiaries who (1) transitioned to Medicare Part D on January 1, 2006, (2) transitioned to Medicare Part D after the initial implementation, and (3) switched from one plan to another after implementation of the Part D program.

appropriate for individuals who require some changes to their medication in order to accommodate PDP formularies.

During the early weeks of the program, CMS received reports that the way in which some PDP sponsors implemented their transition processes adversely affected beneficiaries' ability to obtain transition supplies. Sponsors differed in the time period set for providing transition coverage; some PDPs provided the suggested 30-day supply, while other PDPs provided beneficiaries with as few as a 15-day initial supply. Some PDP sponsors did not apply their transition coverage processes to instances where a formulary drug was subject to utilization restrictions. For example, CMS received complaints that individuals were not given a transition supply when their medications had prior authorization, step therapy, or quantity limit restrictions.⁷¹ Additionally, PDP sponsors' customer service representatives and pharmacies were generally unaware of the transition processes and how to implement them. Pharmacy association representatives also told us of problems overriding the usual pharmacy billing system in order to process a claim when dispensing a transition supply.

CMS responded to the reported problems concerning the uneven application of transition processes by issuing a series of memoranda to PDP sponsors to clarify its expectations.

- On January 6, 2006, CMS issued a memorandum to PDP sponsors highlighting the need for beneficiaries to receive transition supplies at the pharmacy. The memorandum emphasized that PDP sponsors should (1) train customer service representatives to respond to questions about the PDP's transition process, (2) provide pharmacies with appropriate instructions for billing a transition supply, and (3) ensure that enrollees have access to a temporary supply of drugs with prior authorization and step therapy requirements until such requirements can be met.
- On January 13, 2006, CMS issued guidance stating that PDP sponsors should establish an expedited process for pharmacists to obtain authorization or override instructions, and authorize PDP customer

⁷¹Under step therapy restrictions, the PDP requires that the beneficiary first try a less expensive drug for their condition before it will cover the beneficiary's prescribed drug. Under quantity limit restrictions, the PDP limits the amount of the drug it covers over a certain period of time.

service representatives to make or obtain quick decisions on the application of transition processes.

- In a January 18, 2006, memorandum, CMS reiterated its policy that PDP sponsors should provide at least an initial 30-day supply of drugs and that PDPs should extend that coverage even further in situations where a longer transition period may be required for medical reasons. In addition, CMS asked PDP sponsors to consider contacting beneficiaries receiving transition supplies of drugs to inform them that (1) the supply is temporary, (2) they should contact the PDP or physician to identify a drug substitution, and (3) they have a right to request an exception to the formulary and the procedures for requesting such an exception.
- When many beneficiaries continued to return to the pharmacy for refills without having successfully resolved their formulary issues, CMS issued a memorandum on February 2, 2006, calling for an extension of the Part D transition period to March 31, 2006.⁷² The agency asserted that the extension was needed to give beneficiaries sufficient time to work with their provider to either change prescriptions or request an exception.
- In another memorandum to PDP sponsors on March 17, 2006, CMS reemphasized the objectives of the transition process and highlighted the need to inform beneficiaries of what actions to take to resolve formulary issues following the receipt of a transition supply.

Since CMS clarified its transition process guidance to PDP sponsors, many of the issues surrounding transition processes have been resolved. Some of the pharmacy and long-term care associations, and Medicaid officials we spoke with, told us that problems with providing transition drug coverage have largely been addressed. They noted that the issues surrounding the implementation of the transition processes have significantly improved.

To oversee PDP compliance with transition coverage processes, CMS tracks complaints and monitors the time it takes Part D sponsors to resolve complaints. CMS officials said that they rely on beneficiary and pharmacy complaints for information about problems with transition coverage. The agency also assigns case workers to ensure that PDPs

⁷²The extension of the transition period to March 31st was limited to those beneficiaries who were enrolled in the first few months of the program. For those who enrolled on March 1, 2006, or after, the 30-day transition period remained in effect.

resolve these issues. Although CMS can issue monetary penalties, limit marketing, and limit enrollment for PDPs, officials reported that no such punitive actions have been taken against any PDP regarding transition process compliance.

Dual-Eligible Beneficiaries Often Confused about Implications of Receiving Transition Fills

Despite PDP sponsors' efforts to communicate with beneficiaries receiving transition supplies, beneficiaries do not always take needed action during the transition period. Consequently, some dual-eligible beneficiaries return to the pharmacy without having worked with their physician to apply to get their drugs covered or find a substitute drug.

While three PDP sponsors told us how they conveyed information about the transition period, two of these PDP sponsors acknowledged that dual-eligible beneficiaries often do not use the transition period as intended. For example, one PDP executive told us that beneficiaries often do not realize that a transition supply has been provided and that they have to apply to the PDP to continue receiving coverage for that particular drug.

Representatives from some pharmacy associations and long-term care groups that we spoke to also agreed that, even when notified, dual-eligible beneficiaries are unaware of the implications of the policy. Some pharmacy representatives we spoke with noted that when dual-eligible beneficiaries receive a transition supply, they are often unaware that this supply is temporary and therefore return to the pharmacy the following month in an effort to refill the same prescription without having tried to switch to a formulary medication or obtain permission to continue to have the drug covered. Two other pharmacy association representatives noted that beneficiary understanding of transition supplies is a particular problem for dual-eligible beneficiaries in the long-term care setting who often do not open or read the notification letter sent from the PDP. Staff in long-term care facilities often find unopened mail for the beneficiary sent from their PDP.

For 2007, CMS Added Specific Transition Process Requirements to Its Contracts with PDP Sponsors

Unlike the discretion allowed PDP sponsors under the guidance for 2006, CMS's 2007 contract incorporates specific requirements.⁷³ For example, the guidance for 2006 stated that, "we expect that PDP sponsors would consider processes such as the filling of a temporary one-time transition supply in order to accommodate the immediate need of the beneficiary." As part of the 2007 contract, PDP sponsors must attest that the PDP will follow certain required components of a transition process. These components require that, among other things, PDPs

- provide an emergency supply of nonformulary Part D drugs for long-term care residents,⁷⁴
- apply transition policies to drugs subject to prior authorization or step therapy,
- add a computer code to their data systems to inform a pharmacy that the prescription being filled is a transition supply,
- ensure that network pharmacies have the computer codes necessary to bill transition supplies, and
- notify each beneficiary by mail within 72 hours of a transition supply of medications being filled.

To educate beneficiaries about the purpose of transition supplies, CMS also added a requirement for PDP sponsors in its 2007 contracts to instruct beneficiaries about the implications of a transition supply and alert pharmacies that they are supplying a transition supply. Beginning in 2007, PDP sponsors are required to notify each beneficiary of the steps they should take during the transition period when they receive a transition supply of a drug. In addition, PDP sponsors are required to add a computer code to their systems so that after a pharmacist fills a transition supply, a message back to the pharmacist will alert them that the prescription was filled on a temporary basis only. The pharmacist will then be in a better

⁷³In referring to 2007 contracts with PDP sponsors, we are reporting on the attestations PDPs must provide to CMS on transition processes for contract year 2007.

⁷⁴For long-term care residents that are beyond the 90-day transition period afforded to these individuals, the plans must still provide a 31-day emergency supply of nonformulary Part D drugs, including Part D drugs that are on a plan's formulary but require prior authorization or step therapy, while approval is being sought to remain on the drug.

position to inform the beneficiary of the need to take appropriate steps before the transition period ends.

Conclusions

Some challenges regarding the enrollment of new dual-eligible beneficiaries have been resolved, while others remain. In particular, CMS's decision to implement prospective enrollment for new dual-eligible beneficiaries who are Medicaid eligible and subsequently become Medicare eligible should alleviate coverage gaps this group of beneficiaries previously faced. However, because of inherent processing lags, most dual-eligible beneficiaries—Medicare beneficiaries new to Medicaid—may continue to face difficulties at the pharmacy counter. In addition, because of CMS's limited oversight of its retroactive coverage policy, the agency has not been able to ensure efficient use of program funds. Until March 2007, the letters used to notify dual-eligible beneficiaries of their PDP enrollment and their retroactive coverage did not inform them of the right to be reimbursed and how to obtain such reimbursement. CMS monitoring of retroactive payments to PDPs and subsequent PDP reimbursements to beneficiaries is also lacking. We found that Medicare paid PDPs millions of dollars—we estimate about \$100 million in 2006—for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs.

After spending many months stabilizing the information systems supporting the Part D program, CMS is now making changes to improve the efficiency of its key information systems involved in the enrollment process. While CMS officials are aware of the risks involved in these changes, they are not planning to perform end-to-end testing because of the complexity of the systems infrastructure, the multiple partners involved, and time and resource constraints. While we agree that end-to-end testing will be difficult, it is important to perform this testing to mitigate risks and avoid problems like those that occurred during initial program implementation.

CMS's assignment of dual-eligible beneficiaries to PDPs serving their geographic area with premiums at or below the low-income benchmark generally succeeded in enrolling dual-eligible beneficiaries into PDPs. The experience of SPAPs in Maine and New Jersey, while limited, demonstrates the feasibility of using IRA methods to better align beneficiaries' PDP assignments with their drug utilization needs. However, continued use of these methods is contingent on access to beneficiary drug utilization and formulary information from PDPs. In addition, some dual-eligible beneficiaries—those with representative payees—were

assigned to PDPs that did not serve the area where they lived. Since CMS receives a file from SSA that includes an indicator showing that an individual has a representative payee, the agency could use this information to assign these beneficiaries to PDPs that serve the area where they live.

To resolve problems associated with the uneven application of transition policies, CMS clarified its previous guidance to plans and added requirements to its 2007 contracts with PDP sponsors. The 2006 experience with plans' uneven implementation of CMS's transition policy guidance demonstrated how inconsistent interpretations can lead to problems for beneficiaries and pharmacies. CMS officials recognized that the agency needed to be more directive by including specific procedures in its 2007 PDP contracts. Even with consistent implementation of transition policies and notification requirements, however, without assistance, dual-eligible beneficiaries—a highly vulnerable population—are likely to have difficulty resolving problems that they encounter with the transition.

Recommendations for Executive Action

We make the following six recommendations.

To help ensure that dual-eligible beneficiaries are receiving Part D benefits, the Administrator of CMS should require PDP sponsors to notify new dual-eligible beneficiaries of their right to reimbursement for costs incurred during retroactive coverage periods.

To determine the magnitude of Medicare payments made to PDPs under its retroactive coverage policy, the Administrator of CMS should track how many of the new dual-eligible beneficiaries it enrolls each month receive retroactive drug benefits and how many months of retroactive coverage the agency is providing them.

To determine the impact of its retroactive coverage policy, the Administrator of CMS should monitor PDP reimbursements to dual-eligible beneficiaries, and those that paid on their behalf, for costs incurred during retroactive periods through an examination of the prescription utilization data reported by PDP sponsors.

To mitigate the risks associated with implementing Part D information systems changes, especially in light of initial systems issues caused by the lack of adequate testing, the Administrator of CMS should work with key partners to plan, prioritize, and execute end-to-end testing.

To help ensure new dual-eligible beneficiaries are enrolled in PDPs that serve the geographic area where they live, the Administrator of CMS should assign dual-eligible beneficiaries with representative payees to a PDP serving the state that submits the individual's information on their dual-eligible file.

To support states with the relevant authority that want to use alternative enrollment methods to reassign dual-eligible beneficiaries to PDPs, the Administrator of CMS should facilitate the sharing of data between PDPs and states.

Agency Comments and Our Evaluation

CMS reviewed a draft of this report and provided written comments, which appear in appendix II. In addition to comments on each of our recommendations, CMS provided us with technical comments that we incorporated where appropriate.

CMS remarked that we did an excellent job of outlining the complex systems and steps involved in identifying, assigning, and enrolling new dual-eligible beneficiaries into PDPs. However, the agency objected to what it perceived as an overwhelmingly negative tone in our findings and stated that our discussion of retroactive coverage was overly simplified. CMS did note that the agency was in the process of implementing three of our six recommendations to improve existing procedures.

CMS's main concern regarding the draft report for comment centered on our characterization of the interval between the effective date of Part D eligibility and the completed enrollment process as a "disconnect." Also, CMS officials noted that "it is not new or unusual for individuals to pay out of pocket for their prescription drug or other healthcare services, and then subsequently be reimbursed." The agency explained that its policy of tying the effective Medicare Part D enrollment date to the first day of Medicaid eligibility is intended to ensure that dual-eligible individuals receive Part D benefits for the period that they were determined by their state to be eligible for this coverage. CMS asserted that it is the retroactive eligibility requirement under Medicaid, not CMS policy, which causes the "space and time conundrum" over which it has no control.

Regarding this broad concern from CMS, we note that our discussion of the time to complete the enrollment process and the period of retroactive coverage experienced by a majority of newly enrolled dual-eligible beneficiaries was intended to describe CMS's implementation of the enrollment process for new dual-eligible beneficiaries; we did not evaluate

CMS's policy. Recognizing the desirability of providing drug coverage as soon as beneficiaries attain dual-eligible status, we do not object to CMS's policy of linking the Part D effective coverage date to Medicaid's retroactive eligibility date. However, our review found that CMS had not fully implemented this policy and, as a consequence, neither beneficiaries nor the Medicare program are well served. Therefore, we have recommended actions that CMS should take to better protect beneficiaries and ensure efficient use of Medicare program funds. To clarify our message and to reflect information obtained through agency comments, we modified portions of this discussion and provided the revised sections to CMS for supplemental comments.

In its supplemental comments, CMS again objected to what it believed is our implication that retroactive coverage for dual-eligible beneficiaries is inappropriate or that CMS has put the Medicare program at unwarranted risk. As stated above, we do not disagree with the policy of retroactive coverage for dual-eligible beneficiaries; rather we are concerned with how CMS implemented this policy in 2006. Only by monitoring the amounts paid to PDP sponsors for retroactive coverage periods and the amounts PDP sponsors reimbursed dual-eligible beneficiaries will CMS be in a position to evaluate the effectiveness of its retroactive coverage policy.

Also, CMS asserted that we incorrectly imply that CMS had the information needed to monitor reimbursements to dual-eligible beneficiaries when such information is not expected to be available until after May 31, 2007. During the course of our audit work in 2006, CMS indicated no current or planned efforts to monitor or enforce PDP sponsor reimbursements to dual-eligible beneficiaries. Only after receiving our draft report did CMS state its intention to analyze the data necessary to monitor plan compliance and evaluate agency policy. In fact, we were told that CMS decided to conduct this analysis as a direct result of our draft report's findings and recommendations.

CMS agreed with our recommendation to require PDP sponsors to notify new dual-eligible beneficiaries of their eligibility for reimbursement for costs incurred during retroactive coverage periods. To be consistent with its retroactive coverage policy, CMS is in the process of adding language to this effect in the notices that the agency and PDP sponsors send to dual-eligible beneficiaries enrolled in a PDP. The revised letters advise beneficiaries to tell their PDP if they have filled prescriptions since the effective coverage date because they "may be eligible for reimbursement for some of these costs." However, contrary to comments CMS made on our draft report—that dual-eligible beneficiaries will be told they should

submit receipts for previous purchases of Part D drugs—the revised letters do not explicitly tell beneficiaries of the steps they would need to take to access their retroactive coverage. The agency also reported that it plans to inform its partners about the changes to the enrollment notification letters.

In response to our recommendation that CMS determine the number of beneficiaries and the magnitude of payments made to PDP sponsors for dual-eligible beneficiaries subject to retroactive coverage, CMS indicated that it intends to continue to track the number of new dual-eligible beneficiaries provided retroactive coverage. Although this monitoring is important to managing the enrollment process for new dual-eligible beneficiaries, it would be even more useful if CMS tracked the number of months of retroactive coverage provided to beneficiaries it enrolls in PDPs.

CMS disagreed with our recommendation that it monitor PDP reimbursement of beneficiary expenses incurred during retroactive coverage periods. We maintain that the agency should actively monitor its retroactive coverage policy by examining data that plan sponsors routinely submit to the agency. In their drug utilization records, sponsors must indicate the amounts paid by the plan and by the beneficiary for each claim. If it became evident that dual-eligible beneficiaries were not filing claims for retroactive reimbursements while PDPs received Medicare payments for their coverage, CMS would be in a position to evaluate its effective coverage date policy.

Regarding our recommendation that the agency work with key partners to plan, prioritize, and execute end-to-end testing, CMS disagreed and questioned whether the benefits of doing so justify the associated costs. We find this position on end-to-end testing to be inconsistent with systems development best practices. Establishing end-to-end test environments and conducting such tests is widely recognized as essential to ensure that systems perform as intended in an operational environment. CMS was alerted to this issue in a March 2006 CMS contractor report that identified the lack of comprehensive end-to-end testing as a weakness of the Part D program. We acknowledge that, given the complexity of the program's infrastructure and the multiple partners involved, end-to-end testing will be difficult. However, other forms of testing, including integration and stress testing, should be conducted in addition to, not as a replacement for, end-to-end testing.

CMS concurred with our recommendation that it ensure all new dual-eligible beneficiaries are enrolled in PDPs that serve the geographic area where they live. CMS reported that it has completed the underlying changes necessary to implement this recommendation. Beginning in April 2007, the CMS auto-assignment process enrolls dual-eligible beneficiaries into PDPs that operate in the state that submits that individual in its dual-eligible file.

CMS disagreed with our recommendation that the agency facilitate information sharing between PDPs and states that wish to use additional information to reassign beneficiaries yearly. The agency asserted that, for a number of reasons, efforts to match beneficiaries' customary drugs to PDP formularies are not necessary or desirable. Furthermore, CMS noted that it lacks the statutory authority and the drug utilization data needed to assign beneficiaries to PDPs on anything other than a random basis. We did not propose that CMS change its assignment method and we did not take a position on the desirability of states' use of intelligent random assignment methods. However, we maintain that states wishing to reassign beneficiaries should have access to PDP data once beneficiaries have been enrolled.


As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this report. We will then send copies to the Administrator of CMS, appropriate congressional committees, and other interested parties. We will also make copies available to others upon request. This report is also available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact Kathleen King at (202) 512-7119 or kingk@gao.gov. Questions concerning information systems issues and testing should be directed to David Powner at (202) 512-9286 or pownerd@gao.gov. Contact points for our

Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made contributions to this report are listed in appendix III.



Kathleen M. King
Director, Health Care



David A. Powner
Director, Information Technology
Management Issues

Appendix I: Steps Involved in the Identification and Enrollment of Dual-Eligible Beneficiaries into Medicare Part D

The process of enrolling dual-eligible beneficiaries requires several steps: It begins when the state Medicaid agency identifies new dual-eligible beneficiaries and ends when PDPs make billing information available to pharmacies.

1. States are responsible for identifying their Medicaid enrollees who become dual-eligible beneficiaries. They combine data obtained from SSA or requested from CMS on individuals eligible to receive Medicare benefits with their own information on Medicaid enrollees to compile the dual-eligible files. CMS receives Medicare entitlement information daily from SSA.
2. After the 15th of the month and before midnight of the last night of the month, states transmit their dual-eligible files to CMS. These files contain information on all individuals identified by the states as dual-eligible beneficiaries, including those newly identified and those previously identified. Generally within 48 hours of receipt, CMS processes state submissions. Within the Medicare eligibility database, edits of the state files are performed. Based on the results of the edits, the Medicare eligibility database transmits an e-mail to each state telling the state its file was received and the results of the edits. Files that fail the edits must be resubmitted. Once a file passes the edits, the Medicare eligibility database matches the file against the Medicare eligibility database to determine if it is a valid (matched) beneficiary, eligible for Medicare, and passes business rules for inclusion as a dual eligible. The results of this processing for each transaction on the states' file are added to the response files, which are sent back to the states.
3. After CMS has performed the matching process, the Medicare eligibility database processes these files through two additional steps:
 - (a) Deeming. Deeming takes the input from the matching process and a monthly input file from SSA on beneficiaries receiving Social Security Supplemental Income (SSI) to determine the copayment level for the dual-eligible beneficiaries. Deeming is performed against these data according to the business rules.

(b) Auto-assignment. Auto-assignment takes the results of deeming and assigns each beneficiary to a PDP within the region that includes the beneficiary's official address.¹ Auto-assignment takes the total dual-eligible population and eliminates records using 18 exclusions rules resulting in the final set of beneficiaries to be auto-assigned. Exclusions include beneficiaries who are already enrolled in a Part D plan, currently incarcerated, and not a U.S. resident (residing outside the States and territories). Auto-assignment uniformly assigns qualified dual-eligible beneficiaries to designated PDPs across each region.

The resulting deeming and assignment information is sent to CMS's enrollment transaction system for processing. In addition, a mail tape is prepared by CMS containing beneficiary names and addresses so that mail can be generated that informs beneficiaries of the pending enrollment and identifies the PDP to which they were assigned. A file also is sent to each of the plans identifying the beneficiaries assigned to their PDP.

4. Upon the receipt of the deeming and assignment information from the Medicare eligibility database, CMS's enrollment transaction system facilitates the changes in the copayments and the enrollment of the beneficiaries into their assigned PDP. The enrollment transaction system informs the PDP of the enrollment and copayment transactions via a weekly Transaction Reply Report (TRR) that summarizes all transactions that the enrollment transaction system has performed for the respective PDP during the prior week, beginning on Saturday.
5. PDPs then process the resulting assignment and copayment changes, assign standard billing information, and send the information to CMS's Medicare eligibility database. The Medicare eligibility database performs edits, such as matching each submitted beneficiary's information with Part D enrollment information. For each match, the standard billing information is added to the Medicare eligibility database and a response is generated for the PDP, confirming that the information was accepted. The PDPs mail out ID cards and plan information to the enrolled beneficiary.

¹CMS uses the beneficiary's official address as contained in SSA data. This address represents the beneficiary's residence or where the beneficiary's representative payee is located.

**Appendix I: Steps Involved in the
Identification and Enrollment of Dual-Eligible
Beneficiaries into Medicare Part D**

6. Nightly, the eligibility query receives billing information from the Medicare eligibility database, making the updated standard billing information available for use in the eligibility query system.
7. Pharmacies can use their computer systems to access billing information needed to bill the assigned PDP for the beneficiary's prescriptions if a beneficiary does not have their enrollment information.

Appendix II: Comments from the Centers for Medicare & Medicaid Services



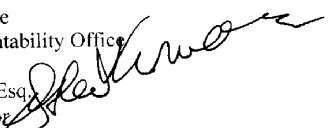
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: FEB 20 2007

TO: Kathleen M. King
Director, Health Care
Government Accountability Office

FROM: Leslie V. Norwalk, Esq. 
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office (GAO) Draft Report: MEDICARE
PART D: Challenges in Enrolling New Dual-Eligible Beneficiaries
(GAO-07-272)

Thank you for the opportunity to review and comment on the above GAO Draft Report. The GAO's study focused on the challenges involved in identifying and enrolling dual-eligible beneficiaries into Medicare prescription drug plans (PDPs) and the Centers for Medicare & Medicaid Services' (CMS) efforts to address these challenges.

We appreciate the GAO's thorough review of the issues involved, as well as the recommendations for fine-tuning the CMS procedures. In particular, the report does an excellent job of outlining the complex systems and steps involved in first obtaining information from States regarding the dual-eligible population and then assigning them to, and enrolling them into, a PDP. CMS welcomes constructive suggestions on how to make this process work better, and we are in the process of implementing some of the report's concrete recommendations. For example, we have taken immediate steps to modify our notice to dual eligibles who are auto-enrolled to further ensure that in situations involving retroactive dual eligibility, they should submit receipts for prescription drug costs incurred during that retroactive period for reimbursement by the plan, as recommended in the report. We have made similar changes to the model notice used by PDP sponsors to confirm the auto-enrollment with their members. Revised notices will be sent to new auto-enrollees beginning in March.

However, this report contains a number of factual inaccuracies and we must object to the overwhelmingly negative tone of the findings set forth in the report, as illustrated in the more detailed comments below. The challenges associated with transitioning the entire dual-eligible population, and all new dual eligibles, to the Part D benefit were immense and largely unprecedented, as you have no doubt become aware in the course of conducting this study. In that context, the report's draft recommendations clearly constitute minor refinements of our existing procedures.

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Thus, we believe that an even-handed report would begin by prominently acknowledging the overall success of CMS' efforts. GAO could begin this report by recognizing the difficulty – indeed the impossibility -- of delivering real time benefits to beneficiaries who become eligible for those benefits retroactively, sometimes by several months. In this respect, the Report could acknowledge that CMS has taken a number of beneficial steps to eliminate the delay that some dual eligibles may encounter in accessing their drug benefits under Medicare.

Instead, the report begins with a finding that is misleading at best: "Some new dual-eligible beneficiaries – generally those on Medicare who have not signed up for a PDP and become eligible for Medicaid – may not access their drug benefit for several months because they are unaware of their coverage." In fact, if a beneficiary is "on Medicare" and has not signed up for a PDP, s/he has no "coverage" until s/he selects a plan or is auto-enrolled. Moreover, the reason beneficiaries may not be aware of the coverage for "several months" is due primarily to the fact that their eligibility for Medicaid, and thus their enrollment in the PDP, is retroactive to the date of their Medicaid application, and often earlier. No beneficiary can be aware of coverage s/he does not yet have and retroactive coverage is not accessible until after it is granted. Rather than explain this complexity, the report simply states: "[T]his is due to a gap between the effective enrollment date and the date beneficiaries receive notice of their coverage." This conclusion is overly simplistic.

That same first paragraph goes on to state that CMS has put the Medicare program "...at risk of paying PDP sponsors for several months when they are not providing drug benefits." Please be advised that this conclusion is unsubstantiated and factually incorrect. PDP sponsors, in fact, have an obligation to reimburse their members (or another payer) for costs incurred retroactively when the sponsor is the primary payer. We have also educated our partners about this policy, so that they can help to ensure that dual-eligible beneficiaries understand their right to reimbursement for retroactive costs. As discussed above, we have taken additional steps to ensure that beneficiaries are aware of their right to request such reimbursement. Therefore, given the GAO's full awareness of both the retroactivity of Medicaid eligibility determinations and the statutory prohibition on Medicaid payments for Part D drugs, we consider any implication that CMS is somehow overpaying PDP sponsors to be inappropriate. Legally, CMS cannot require PDPs to provide retroactive coverage without paying a premium to the PDPs for the period of retroactive coverage. Thus, under current law, the only way to avoid such payments would be to establish a prospective effective date for drug coverage for these individuals. However, such a policy would effectively preclude dual-eligible individuals from any drug coverage during a period when they were determined by the State to be eligible for such coverage.

We address each of the report's "Recommendations for Executive Action" in the attached document, followed by more detailed technical comments.

Attachment

**Centers for Medicare & Medicaid Services' (CMS) Comments to the Government
Accountability Office's (GAO) Draft Report: MEDICARE PART D: Challenges in
Enrolling New Dual-Eligible Beneficiaries (GAO-07-272)**

GAO Recommendation 1: To help ensure that dual-eligible beneficiaries are receiving Part D benefits, the Administrator of CMS should require PDP sponsors to notify new dual-eligible beneficiaries that they are eligible for reimbursement for costs incurred during retroactive eligibility periods.

CMS Response: We agree with this recommendation and, as noted above, have inserted language to this effect in the notices that CMS and prescription drug plan (PDP) sponsors send to dual-eligible beneficiaries who are auto-enrolled into a plan. Again, we have also educated our partners about this policy, so that they can help to ensure that dual-eligible beneficiaries understand their right to reimbursement for retroactive costs. However, we object to the report's repeated references to "disconnects between CMS' enrollment policies for dual-eligible beneficiaries and the enrollment processes" (first paragraph under "Results in Brief," page 6), "Incongruent Enrollment Policies and Enrollment Processes" (Heading, page 18), "Disconnect Between Effective Enrollment Date and Completed Enrollment Process" (Heading, page 19), etc. As GAO notes, CMS policy is that, for Medicare-eligible individuals who subsequently become Medicaid-eligible, the effective date of enrollment is tied to the first day of the month of Medicaid eligibility. CMS established this policy to ensure that these beneficiaries do not experience a gap in drug coverage. We are very interested in whether GAO objects to this policy in any way or if GAO has any constructive recommendations to address the real space and time conundrum that beneficiaries face with retroactive Medicaid benefits, a situation over which Medicare has no control. If so, we would welcome a recommendation to that effect, or a suggested alternative approach. If not, we believe that the repeated implications that CMS' implementation of this policy is the source of problems should be eliminated.

Our continued belief is that, by statute, only PDP sponsors and not the Medicaid program can legitimately pay the drug costs for dual-eligible individuals. Thus, given the need to provide drug coverage for dual-eligible individuals as soon as they attain dual-eligible status, the logistical realities of obtaining dual-eligible data from States, and the ongoing reality of retroactivity in State Medicaid eligibility procedures, we believe that reimbursing PDPs for these retroactive months is the only viable approach. As GAO has suggested, making beneficiaries aware that they can save and submit receipts after eligibility is determined is consistent with this approach.

GAO Recommendation 2: To estimate the potential magnitude of payments to PDP sponsors for time periods when dual-eligible beneficiaries cannot access their drug coverage, the Administrator of CMS should determine how many new dual-eligible beneficiaries each month or year are Medicare beneficiaries who subsequently qualify for Medicaid, and of those how many were previously enrolled in a PDP. The Administrator of CMS should also determine how many months of retroactive coverage the agency is providing to new dual-eligible beneficiaries.

CMS Response: As the GAO report notes on page 34, CMS has implemented prospective enrollment for Medicaid-eligible individuals who then attain Medicare eligibility; thus, we can readily identify the other population—the Medicare first, Medicaid second group—and those within that group who are already enrolled in a PDP. Factoring out the existing Part D enrollees is an ongoing part of our monthly auto-enrollment process. We have every intention of continuing to track these enrollments, and can use this information to determine how many months of retroactive coverage the Agency is providing to new dual-eligible beneficiaries.

However, we do not agree that these individuals are necessarily unable to access their drug coverage. As noted above, retroactive eligibility is a long-standing element of the Medicaid program, and thus it is not new or unusual for individuals to pay out of pocket for their prescription drug or other health care services, and then subsequently be reimbursed. In fact, retroactivity of benefits has been a longstanding consideration that has been built into the business models of many providers, especially Long Term Care providers. In this respect, retroactivity of benefits is not new or unusual for many providers who are now serving these beneficiaries under Part D.

GAO Recommendation 3: To reduce the risk of Medicare making payments to PDPs for time periods when dual-eligible beneficiaries cannot access their drug benefit, the Administrator of CMS should monitor PDP reimbursements to dual-eligible beneficiaries and those that paid on their behalf for costs incurred during retroactive eligibility periods through an examination of the prescription utilization data reported by PDP sponsors.

CMS Response: We disagree with GAO about the level of “risk” associated with Medicare making payments to PDPs for time periods when dual-eligible beneficiaries cannot access their drug benefit. As already discussed, we do not believe that there are any viable alternatives to making payments to PDPs for individuals who become dual-eligible on a retroactive basis. PDP sponsors have an obligation to reimburse their members (or another payer) for costs incurred retroactively when the sponsor is the primary payer. Furthermore, as GAO has already suggested, making beneficiaries aware at the time they are notified of their auto-enrollment that they may collect and submit receipts upon confirmation of eligibility will substantially reduce any risk or inefficiencies in paying PDPs for the entire time beneficiaries are allowed to access the benefit retroactively. Therefore, we have made appropriate changes to the notices sent by CMS and the PDP sponsors to new dual-eligible beneficiaries. As noted above, we have already educated our partners about this policy, and we are letting them know about the upcoming changes in the letters, so that they can continue to help ensure that dual-eligible beneficiaries understand their right to reimbursement for retroactive costs.

GAO Recommendation 4: To mitigate the risks associated with implementing Part D information systems changes, especially in light of initial systems issues caused by the lack of adequate testing, the Administrator of CMS should work with key partners to plan, prioritize, and execute end-to-end testing.

CMS Response: While we agree that there are benefits to “end-to-end” testing, we believe that the benefits to be achieved from conducting “end-to-end” testing in the Medicare Part D systems environment are highly questionable, particularly given the prohibitive expenses and resources involved in staging and re-setting the testing environments across CMS and external parties. Thus, CMS has instead focused upon thorough integration testing and stress testing of the key interfaces that are required to keep the entire process working correctly. In fact, this testing has identified significant issues that were dealt with during the initial start-up, the resulting corrections, and the work underway now to further integrate key systems and databases.

As CMS continues to test interfaces between systems within our environment, we would appreciate any specific recommendations GAO has to offer in this area. For example:

- How would the GAO propose setting up and managing an appropriate test environment and test databases, which would have to be synchronized across all the entities who were party to the testing?
- Could GAO give cost estimates involved in setting up such end-to-end testing environments, processes and scenarios as well as estimate the marginal benefit that would be achieved over the testing that is currently done?
- The GAO does suggest prioritizing such testing considering factors such as the “willingness of external parties to participate.” If we were to set up the environment, engage 1 or 2 States, 1 or 2 plans, the TrOOP Facilitator, SSA, and all other parties to participate, what would a successful test prove? What assurances would such testing produce other than that beneficiaries in those particular States who were enrolled in those particular plans were handled correctly under those particular circumstances? This testing would offer no assurance that the full range of beneficiaries, States, plans, and other parties would also work correctly.

GAO Recommendation 5: To help ensure new dual-eligible beneficiaries are enrolled in PDPs that serve the geographic area where they live, the Administrator of CMS should assign dual-eligible beneficiaries with representative payees to a PDP serving the state that submits the individual’s information on their dual-eligible file.

CMS Response: CMS agrees with this recommendation and has completed the underlying systems changes necessary to implement this change. Beginning in April 2007, the CMS auto-assignment process will assign all dual-eligible beneficiaries to PDPs in the State that submits that individual in its dual-eligible file. However, we would also note that we currently have procedures in place designed to ensure that PDPs take appropriate steps to ensure enrollment in the region of residence and continuity of coverage until any needed enrollment changes take place.

GAO Recommendation 6: To support states with the relevant authority that want to use alternative enrollment methods to reassign dual-eligible beneficiaries to PDPs, the Administrator of CMS should facilitate the sharing of data between PDPs and the states.

**Appendix II: Comments from the Centers
for Medicare & Medicaid Services**

CMS Response: All PDPs have comprehensive formularies that are reviewed by CMS to ensure that they can meet the prescription drug needs of their enrollees; thus we do not accept the premise that exact drug matches are necessary or desirable. CMS recommends that the GAO examine the assignment processes in Maine and New Jersey to see what results would have occurred if the State matched their individuals' formularies to plans' formularies, including therapeutic (generic) alternatives, and determined how many plans could have accommodated the beneficiary's drug regimen by switching to generic alternatives. This would result in savings to plans and eventually the Federal and State governments. Maine has assumed that the beneficiaries' drug regimen was the most appropriate for the beneficiary and the most cost-effective for the State prior to the random assignment. This conclusion is not necessarily supportable by available evidence.

Moreover, unlike Maine and other States, CMS does not have access to prescription drug utilization data for beneficiaries prior to their becoming eligible for Medicare and enrolling in a Part D plan. Thus, even if CMS had the statutory authority to auto-enroll these beneficiaries into Part D plans on anything other than a random basis, we could not adjust our auto-enrollment process to take into account beneficiaries' prior drug utilization, as some States have done. Given that dual eligibles have the ability to change plans at any time, we continue to believe that these beneficiaries, and the people who work with them, are best suited to make these choices. We believe that re-assignments at this point are likely to result in beneficiary confusion and create unnecessary transition issues for this population.

We would also note that we have already worked with several States and State Pharmaceutical Assistance Programs (SPAPs), including in Maine and New Jersey, to assist in the assignment and enrollment of their populations and will continue to do so; but, in all these cases, States were in possession of the relevant drug utilization information.

**Appendix II: Comments from the Centers
for Medicare & Medicaid Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR 12 2007

TO: Kathleen M. King
Director, Health Care
Government Accountability Office

FROM: Leslie V. Norwalk, Esq. *LNorwalk*
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office (GAO) Draft Report: MEDICARE
PART D: Challenges in Enrolling New Dual-Eligible Beneficiaries
(GAO-07-272) (Revised)

Thank you for the opportunity to review and comment on the revised sections of the draft report entitled: *MEDICARE PART D: Challenges in Enrolling New Dual-Eligible Beneficiaries*. Our understanding, based on your April 6, 2007 letter, is that the revised material will replace in its entirety the section formerly entitled, "Medicare Makes Payments to PDP Sponsors When Beneficiaries Cannot Access Coverage," but that the related material in the earlier sections of the report is essentially unchanged.

Thus, as discussed in detail in our February 20, 2007 response, we continue to object to any implications that retroactive coverage for dual eligible beneficiaries is somehow inappropriate or that CMS has somehow put the Medicare program at unwarranted risk. Again, we note that GAO apparently supports this retroactive payment policy, given the lack of any recommendation to the contrary. We respectfully suggest that a fair-minded report would acknowledge this simple but critical fact.

It is also important to note that the revised report incorrectly indicates that CMS has had access to evidence that would permit monitoring of reimbursements to dual eligible individuals for drug purchases made during retroactive periods (Page 5, first full paragraph). Our first opportunity to compare these so-called "PDE data" (prescription drug event data) for individuals enrolled retroactively will not come until after May 31, 2007, and we intend to carry out the analysis in question at that time. Thus, as further elucidated below, we strongly disagree with the conclusion on page 6 that CMS' monitoring of retroactive payments and reimbursements has been "lacking."

Appendix III: GAO Contacts And Staff Acknowledgments

GAO Contacts

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