IMPROVING THE MEDICARE PART D PROGRAM FOR THE MOST VULNERABLE BENEFICIARIES

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ABSTRACT: Prescription drug coverage became available under Medicare for the first time in 2006 under Medicare Part D—the most significant change in government health care programs in 40 years. While it offers the potential for improved access to needed medications for millions of Americans, Part D has had both successes and challenges. With the program now in its second year, researchers have the opportunity to learn from experiences and strengthen the program, particularly as it affects the frailest, sickest, and most vulnerable beneficiaries. Although 13.2 million beneficiaries are eligible for a low-income subsidy to help pay for premiums and medication copayments, 3.3 million of this group are not enrolled in Part D and not receiving the subsidy. This report discusses some of the challenges vulnerable Medicare beneficiaries face in using Part D and makes specific recommendations, like using simpler, more standard procedures and ensuring that needed counseling support is provided.

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EXECUTIVE SUMMARY

In 2006, prescription drug coverage became available under Medicare for the first time. Called Medicare Part D, the program is the most significant change in government health care programs in 40 years, offering the potential for improved access to needed medications for millions of Americans.

The new program has had success, but has also faced daunting challenges. Researchers now have a chance, early in Part D's second year, to learn from the experience to date and to strengthen the program, particularly as it affects the frailest, sickest, and most vulnerable beneficiaries, including nursing home residents.

The complexity of the program poses particular challenges for "dual eligibles"—Medicare beneficiaries who also qualify for Medicaid benefits. These beneficiaries, most of whom previously had received drug coverage through Medicaid, were switched to Medicare coverage under Part D and auto-assigned to eligible plans beginning January 1, 2006.

Although dual eligibles had the option to switch to a different plan for their drug coverage if they preferred, they were not necessarily in a good position to effectively do so. In addition to having the lowest incomes, this group disproportionately includes beneficiaries with multiple chronic conditions that result in high prescription drug usage: dual eligibles average 10 more prescriptions per month than other beneficiaries. They are the least-educated group of Medicare beneficiaries and are the most likely to be limited in English proficiency. In addition, a disproportionately high percentage of dual eligibles have cognitive impairments.

Although 13.2 million beneficiaries are eligible for a low-income subsidy that helps pay the premiums for Part D and the copayments for medications, 3.3 million of this group are not receiving the subsidy and are not enrolled in Part D. Administrators must find better ways to reach out to those beneficiaries, simplify the enrollment process, and assist beneficiaries in navigating that process. Better communication and closer monitoring of the program's operations would help enhance its quality and increase its value to beneficiaries.

The implementation of the Part D program was a huge undertaking accomplished very quickly. Unlike other benefits available under traditional Medicare, Part D is administered through almost 1,900 stand-alone prescription drug plans (PDPs). The number of PDP options ranges from 45 to 66, depending on where the beneficiary lives.

Part D coverage is also available through more than 1,000 private Medicare Advantage Part D plans (MA-PDs) that provide Part A (hospital insurance) and Part B (supplementary medical insurance), as well as Part D prescription drug benefits.

Plans differ from each other in design; in costs of premiums, deductibles, and coinsurance or copayments; in formulary composition; and in the process for obtaining coverage for drugs not included in the formulary. In addition, Part D plans have broad discretion, within certain statutorily prescribed parameters, to decide which drugs to include in their formularies; the strengths and dosage forms of covered drugs to include; and the types of "utilization management processes" used to control drug costs and usages.

To complicate the process even more, a number of entities are involved in the administration of the Part D program: The Centers for Medicare and Medicaid Services (CMS) administers the Medicare program and has overall responsibility for Part D; the Social Security Administration and state Medicaid offices have primary responsibility for approving applicants for the low-income subsidy; Part D plans provide the benefits; physicians prescribe medications based on plan design; and pharmacies fill the prescriptions.

Under utilization management, plans may establish different copayments for different drugs: "tiered pricing" distinguishes among preferred drugs, non-preferred drugs, generic drugs, and specialty drugs. Plans may also limit the number of pills or dosage amounts; require that beneficiaries request prior authorization for covered prescription drugs; or require that they try particular medications included in the plan's formulary before those prescribed by the physician ("step therapy").

Some evidence suggests that utilization management techniques have caused delays or otherwise restricted access to prescription medications, including mental health drugs. These techniques have the potential to cause disastrous outcomes in patients—particularly the most vulnerable.

This report discusses some of the challenges vulnerable Medicare beneficiaries face in using Part D and makes specific recommendations to strengthen the program in certain areas (box). Legislative authority is needed to accomplish some of these changes, such as eliminating or amending the resource test, changing the rules for individuals needing long-term care services, and ensuring that funds for counseling are appropriately available. Legislative changes would also be useful to ensure that current drug regimens are considered when auto-enrollment occurs. In the interim, a different regulatory interpretation of certain legal provisions could help. Most of the other changes that are needed could be accomplished administratively.

Recommendations to Strengthen Part D Program Areas

The Low-Income Subsidy

- Eliminate or amend the resource test
- Provide enrollment encouragement and assistance
- Monitor redeeming and redetermination

Transition from Medicaid to Medicare

- Use available information in making plan assignments
- Simplify the transition process by extending the supply of non-formulary drugs
- Expand the "point-of-service" system

The Use of Formularies and Utilization Management Tools

- Improve the coverage determination process
- Use simpler, more standard procedures

Part D and Long-Term Services and Supports

- Ease the process to get appropriate drugs to nursing home residents
- Extend protections for nursing home residents to individuals in the community

Program Quality

- Strengthen electronic communication
- Provide program information in new ways
- Ensure support for counseling

These beneficiaries are the least able to understand how to pursue an exception request or other coverage determination. Some changes to current practices could help beneficiaries and those who assist them resolve problems related to the coverage of specific drugs. Concerted efforts to inform beneficiaries about the coverage determination process, for example, would be helpful, as would standardization of the procedures and criteria used in the exceptions and appeals process.

Experience in 2006 suggests additional steps that could be taken to ensure that the Part D program operates more effectively. More monitoring on the part of CMS is needed, and the government should take steps to strengthen electronic communication systems, provide program information in new ways, and ensure that beneficiary counselors are available, particularly for the frailest, sickest, and most vulnerable.

IMPROVING THE MEDICARE PART D PROGRAM FOR THE MOST VULNERABLE BENEFICIARIES

BACKGROUND

The creation of Medicare Part D has provided an opportunity for improved access to prescription drugs for many Medicare beneficiaries, particularly for those who previously had no drug coverage. Many beneficiaries, however, have encountered numerous, significant difficulties as they attempt to enroll in the program or use the benefits it offers. The implementation of the Part D program was a huge undertaking accomplished very quickly. After a year of experience, researchers have sufficient information to begin identifying ways that the program could be made to work better for all beneficiaries.

Unlike other benefits available under traditional Medicare, Part D is administered through almost 1,900 stand-alone prescription drug plans (PDPs). The number of PDP options ranges from 45 to 66, depending on where the beneficiary lives.[1] Beneficiaries also have the option of receiving Part D coverage through more than 1,000 private Medicare Advantage (MA) plans that provide Part A (hospital insurance), Part B (supplementary medical insurance), and Part D (prescription drug) benefits. Plans differ from each other in design; in costs of premiums, deductibles, and coinsurance or copayments; in formulary composition; and in the process for obtaining coverage for drugs not included in the formulary.

The complexity of the program poses particular challenges for dual eligibles: Medicare beneficiaries who also qualify for Medicaid benefits. These beneficiaries, most of whom had previously received drug coverage through Medicaid, were automatically switched to Medicare coverage under Part D and randomly assigned to an eligible PDP or MA plan beginning January 1, 2006. Although dual eligibles had the option to switch to a different PDP or MA plan for their drug coverage if they preferred, they were not necessarily in a good position to effectively exercise that option. In addition to having the lowest incomes, this group disproportionately includes beneficiaries with multiple chronic conditions requiring high prescription drug usage: dual eligibles average 10 more prescriptions per month than other beneficiaries.[2] They are also the least-educated group of Medicare beneficiaries and the most likely to be limited in English proficiency.[3] In addition, a very high percentage of dual eligibles have cognitive impairments.[4]

The early stages of implementation of the Part D benefit involved some major difficulties—particularly for dual eligibles—as the Centers for Medicare and Medicaid Services (CMS) dealt with a number of operational problems. Most state governments

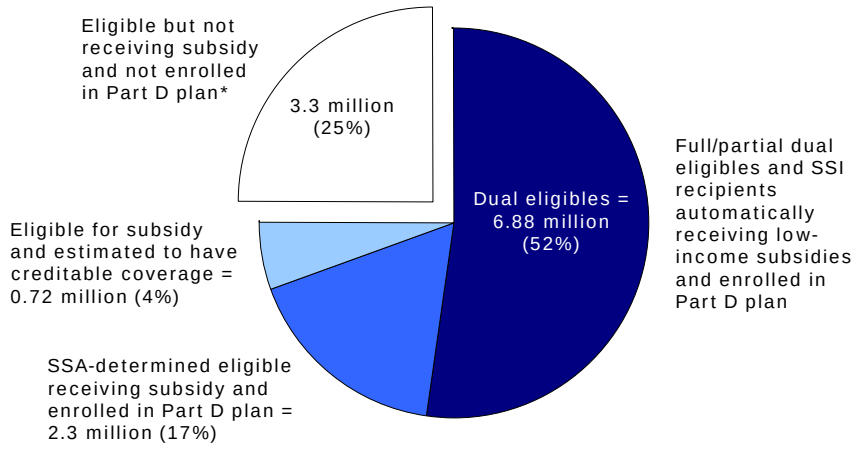
responded to these problems by providing temporary assistance for all or part of 2006 to vulnerable Part D beneficiaries who experienced difficulties in obtaining medications, and public and private organizations worked tirelessly to reach and counsel such beneficiaries. Now is an opportune time, as the prescription drug benefit enters its second year, to examine program operations and identify which policy and administrative changes could potentially ensure the program works more effectively for dual eligibles and other vulnerable Medicare beneficiaries.

THE LOW-INCOME SUBSIDY: STRATEGIES TO INCREASE ACCESS

The Part D low-income subsidy is a valuable aspect of the Part D program that has the potential to help some of the most needy beneficiaries obtain drug coverage.[5] The subsidy is available to beneficiaries with incomes up to 150 percent of the federal poverty level ($1,271 per month in 2007) and limited resources, and provides substantial help through payments of plan premiums and prescription cost-sharing. Millions of those eligible for the LIS, however, are not enrolled or benefiting from it.

The latest estimates released by CMS indicate that 13.2 million beneficiaries are eligible for the subsidy. But 3.3 million beneficiaries—one-quarter of all who are eligible and one-half of those who are eligible but were not automatically enrolled—are not receiving the subsidy and are not enrolled in a Part D plan (Figure 1).[6] The Department of Health and Human Services reported in June 2006 that a total of 4.4 million Medicare beneficiaries were not enrolled in Part D and had no identified source of creditable coverage; the great majority of them—about 75 percent—appeared to also qualify for the subsidy.[7] Moreover, other low-income beneficiaries who are enrolled in Part D may not be receiving the subsidy for which they might be eligible.

Figure 1. CMS Estimates of Eligibility and Participation in the Medicare Part D Low-Income Subsidy



Beneficiaries Eligible for Low-Income Subsidy = 13.2 Million

* Includes future anticipated facilitated enrollment of 0.03 million beneficiaries.
Source: Centers for Medicare and Medicaid Services, "Medicare Drug Plans Strong and Growing," press release (Washington, D.C.: CMS, Jan. 30, 2007).

To increase access to the subsidy for those who need it, policymakers could consider eliminating or amending the resource test; providing financial and other support for programs that assist beneficiaries with the enrollment process; and stepping up monitoring efforts to ensure that qualified beneficiaries do not lose their subsidy when it is time to re-assess their eligibility.

Eliminate or Amend the Resource Test

The government's resource test deters beneficiaries from qualifying for the low-income subsidy. A review conducted by the Social Security Administration (SSA) in January 2006 showed that more than half (57%) of those applying for the subsidy who would have qualified based on income were determined ineligible because their resources exceeded the eligibility requirement. Bank accounts were the most common source of excess resources for these applicants.[8] Another recent study corroborates this, indicating that most applicants who meet the income but not the resource limits for the low-income subsidy have relatively modest assets that tend to be in bank accounts.[9] These individuals with very low incomes are being penalized because they saved their money, often in anticipation of health-related expenses in later life.

In addition to blocking coverage for some very needy beneficiaries, use of a resource test increases the complexity of the application process. Applicants may not complete the process if they do not understand what is required or cannot produce information pertaining to the value of assets such as life insurance policies. The need to verify the value of resources also imposes an administrative burden on SSA.

Legislation to eliminate the resource test would solve these problems for beneficiaries and significantly reduce the administrative burden on SSA. Short of elimination, other changes could make the test less onerous and fairer. For example, SSA could increase the amount that is disregarded in calculating the value of countable assets. Precedent for this exists in the Medicare Savings Programs (MSPs), which help with Part B premiums and copayments for other Medicare services. In administering those programs, 10 states have established exclusions higher than the standard $1,500 for life insurance or burial funds to determine program eligibility.[10]

The treatment of retirement funds also deserves consideration. For the relatively small proportion of people with low incomes who have retirement plans, current rules favor defined benefit rather than defined contribution plans, because the present value of future benefits is not counted as an asset for the former but is for the latter. A more equitable approach would be to include the estimated payment from defined contribution retirement funds in calculating incomes and not to count retirement funds at all when calculating resources. SSA has already demonstrated its willingness to modify rules used by the Supplemental Security Income (SSI) program (the link to which is made in the Part D statute) by eliminating non-liquid resources, such as automobiles, from its calculations.

At a minimum, SSA should make certain data available so that policymakers can assess the impact of the resource test on program participation. It would be helpful, for example, if the agency periodically reported the proportion of applicants who qualify for the subsidy based on income, but not on resources, and characterized the types and amounts of resources reported for that group.

Provide Enrollment Encouragement and Assistance

Even though the low-income subsidy is an aspect of the Part D program, its application process is entirely separate from the Part D plan enrollment process and both are difficult to navigate. As a result, some of the most vulnerable beneficiaries have to complete two complex processes to benefit from the Part D program.

The fact that millions of eligible beneficiaries do not receive the subsidy suggests the need for more efforts to publicize it. The increased availability of information materials, applications, and correspondence in languages in addition to English is one recommendation frequently made by organizations working in the community. For example. SSA makes sample subsidy applications available in 15 languages for information purposes, but only has the capacity to accept scannable English and Spanish versions for processing.

Also needed are support for one-on-one counseling and the involvement of community-based organizations in providing assistance and counseling. Finally, some simple changes in procedures could make the application process less daunting. SSA could amend the language used on the subsidy application, for example, to eliminate references to prison as the penalty for perjury. Language commonly found on other applications merely certifies the truth under penalty of perjury, without the unnecessarily threatening mention of prison time.

Monitor the Redeeming and Redetermination Processes

Finally, it is important to consider the processes for reassessing eligibility for the low-income subsidy.[11] Ensuring that the subsidy continues uninterrupted for eligible individuals is a significant goal. Otherwise, beneficiaries must reapply for subsidies and may have to go without the needed benefit while they wait for re-approval. Some of the associated problems that occurred during early implementation of the benefit—not understanding that a two-part process is required to apply for a subsidy and enroll in a plan; random assignment to plans with inappropriate formularies or inaccessible pharmacies; long waits for plan cards; and delays in system updates—may occur again. If such difficulties arise, SSA, CMS, drug plans, and pharmacists will be unnecessarily burdened with the need to reconcile subsidy and plan enrollment status.

Eligibility for the low-income subsidy will automatically extend through December 2007 for Medicare beneficiaries who were deemed and remain eligible because they still qualify for Medicaid, MSPs, SSI, as well as Medicare. CMS, however, notified approximately 630,000 beneficiaries that they would not be automatically eligible for the subsidy in 2007 because of changes in their Medicaid, MSP, or SSI eligibility status.[12] These individuals—who likely are particularly vulnerable considering that they recently qualified for one of those benefits—have to file a new application for the subsidy. Many of these individuals will still qualify for the subsidy. The likelihood that individuals deemed eligible will "churn" off and on the subsidy program could be reduced if CMS, before terminating benefits, were required to screen individuals losing deemed status for all possible subsidy eligibility categories, and if those whose subsidy is terminated had the procedural right to appeal the decision.

By law, SSA is required to redetermine eligibility for the low-income subsidy within one year of the initial determination. In the fall of 2006, SSA sent letters to beneficiaries receiving the subsidy asking them to review information that it had on file for them and explaining that if circumstances had not changed, no response was necessary. Those beneficiaries for whom circumstances had changed were asked to return a form

indicating how their circumstances had changed so that SSA could make a redetermination regarding eligibility. In subsequent years, redeterminations will occur at different intervals depending on SSA's assessment of the likelihood that circumstances affecting an individual's eligibility will change.[13] SSA has not yet announced what methods will be used to establish the intervals. Experience from other programs should be considered. Research shows, for example, that a substantial proportion of older low-income Medicare beneficiaries remain eligible for MSP benefits year after year.[14] In addition, after the first and subsequent redeterminations, SSA will be able to track outcomes and base policy on that information. The process could be further simplified by eliminating the resource test at the time of redetermination.

A Missed Opportunity:
Screening for Low-Income Medicare Beneficiaries

Medicare beneficiaries have the option of applying for the low-income subsidy either through SSA or the state Medicaid office. SSA, CMS, and the states, through all their outreach and guidance materials on the subsidy, promoted SSA as the place to apply for the benefit, despite the statutory requirement that states, not SSA, screen subsidy applicants for Medicaid and MSP eligibility. As a result, nearly all applications to date have been processed through SSA.[15] Few subsidy applicants have been screened for Medicaid or MSP. A recent comparison of the subsidy and MSP eligibility and enrollment rules indicates that each application site has certain advantages, but concludes that applying for the subsidy at the state agency will almost always be more beneficial to the applicant because of the screening mandate and because, particularly in some states with more liberal MSP eligibility standards, individuals who are not otherwise eligible for the subsidy may qualify through the MSPs.[16] Federal mandates for SSA to screen for Medicaid eligibility or for SSA to forward specific eligibility information from the subsidy application to the Medicaid office for review and processing could provide additional assistance to very vulnerable Medicare beneficiaries. In addition, Medicare beneficiaries who apply for Medicaid benefits but do not qualify should have the opportunity to have their Part D and subsidy eligibilities determined based on the information they already have provided to Medicaid.

EASING THE TRANSITION FROM MEDICAID TO MEDICARE COVERAGE

Medicaid beneficiaries' prescription drug coverage automatically shifts to Medicare when they became newly eligible for Medicare Part D. In anticipation of this transition, and in recognition of the fact that dual eligibles are a vulnerable population whose access to prescription drug coverage is essential, the Medicare Modernization Act contains specific protections to maintain seamless coverage. The Act directs CMS to assign all dually

eligible beneficiaries who do not choose a plan on their own to plans randomly selected among the qualifying plans in the beneficiaries' region.[17] The act also provides that dual eligibles may switch plans at any time.[18] This right to switch plans is important because random assignment may result in duals being assigned to plans that do not meet their needs.[19] An initial large shift from Medicaid to Medicare of more than 6 million dually eligible beneficiaries occurred in January 2006. Problems at that time resulted in denied access to drugs and interrupted care for many people.[20]

The shift from Medicaid to Medicare coverage is ongoing as Medicaid beneficiaries continue to qualify for Medicare. In California alone, tens of thousands of Medicaid beneficiaries become eligible for Medicare each month.[21] Another reason for a change in drug coverage is that beneficiaries who receive the low-income subsidy will be annually reassigned to another plan if they are enrolled in plans that have premiums above the benchmark established by CMS. Almost 250,000 beneficiaries were affected in this way in 2007.[22] Reassignment also occurs when dually eligible beneficiaries are enrolled in plans that leave the market.

Recommendations to ease some of the difficulties that have been associated with the transition process include the use of information to match beneficiaries' needs with plans' offerings during the auto-enrollment process, simplification of the transition process, extension of the time period when initial supplies of non-formulary drugs are available, and enhancements to the "point-of-service" system.

Make Beneficiary-Focused, "Random" Part D Plan Assignments

Random assignment, as it presently occurs, does not take into account beneficiaries' prescribed drugs or pharmacy usage. A different approach could take advantage of the fact that Medicaid programs already have information about the particular drugs that beneficiaries take. The use of this information to match beneficiaries with Part D plans should be considered. Although the statute uses the word "random" with respect to the auto-enrollment, CMS could interpret that word to mean random among those plans that meet the beneficiary's needs. In fact, CMS already has approved the use of beneficiary-centered assignment by at least six state pharmacy assistance programs and one state Medicaid program.[23] An assignment that is made effective immediately and takes into account the individual's drug and pharmacy usage would substantially reduce the problems that dual eligibles faced in 2006 with respect to access to drugs.

Auto-Enrollment and Pharmacy Access: Special Challenges for Rural Residents

Medicare beneficiaries in rural areas—not just those who are dually eligible—have had trouble finding pharmacies where they live that participate in their Part D plans. Current requirements for geographic access in rural areas are only that 70 percent of beneficiaries live within 15 miles of a pharmacy.[24] This minimal and inadequate pharmacy access requirement, together with random auto-enrollment that does not take place of residence into account (but which is limited to qualifying plans with premiums below the regional benchmark), results in lack of meaningful access to pharmacies for some dual eligibles. More stringent geographic participation requirements, together with more targeted auto-enrollment, could improve access to pharmacies for dual eligibles as well as other Medicare beneficiaries.

Extend, Simplify, and Publicize the Transition Process

Every Medicare Part D drug plan must have a process to address the needs of new enrollees who are, at the time of enrollment, using medications not included on the plan's formulary. For 2006, CMS guidance recommended, but did not require, that plans provide a temporary 30-day supply of non-formulary medications.[25] The purpose of the transition supply was to allow beneficiaries time to change to a formulary drug or ask for an exception to the formulary exclusion of the drug. Dual eligibles who are randomly auto-enrolled in plans are particularly likely to need this type of assistance, since auto-enrollment does not take into account their specific drug needs.

For 2007, CMS guidance changed the recommendation to a requirement for a 30-day supply of non-formulary drugs.[26] A 30-day period may be an insufficient amount time, however, for beneficiaries to obtain prescriptions for alternative medications, work with their physicians to determine the efficacy of the new medication, and, if necessary, request an exception to receive coverage for the original medication. A longer transition time—such as 90 days—is more appropriate, as suggested by the CMS 2007 guidance for transitions for nursing home residents, which requires monthly refills of transition supplies through the first 90 days of plan enrollment.[27]

Although beneficiaries had a great need for temporary supplies of medications in the early months of the Part D program, the option of requesting initial supplies of non-formulary drugs generally was not used because information on the various processes established by the plans was not readily available, and the processes were confusing and difficult to use. Pharmacists indicated that they were advancing enormous quantities of prescription medicine and were financially at risk.[28] CMS urged plans to voluntarily

extend temporary supplies of medications through March 2006,[29] and more than 40 states stepped in to provide backup emergency assistance for their Medicaid populations.[30] Some states continue to provide more limited assistance.[31]

The lack of clear information for beneficiaries about what they needed to do after receiving a "transition" supply of drugs added to the complexity of using a plan's transition process. Absent clear notice about the next step, some beneficiaries arrived at the pharmacy after their transition supply ended to find that their drug would not be paid for. Information about the plans' transition processes is still not readily available.[32] If the use of a standard transition process were mandated and publicized, beneficiaries and those who assist them would be much more likely to be informed, understand the process, and ultimately benefit from it. Absent a single process, the transition requirements and procedures for each drug plan should be on the CMS's and plans' Web sites, and an easily understood written summary should be provided to all plan members in a timely manner.

Strengthen and Expand the Point-of-Service System

In 2005, prior to 2006 auto-enrollment, CMS created a "point-of-service" system to help dual eligibles who were not assigned to plans.[33] If dual-eligible beneficiaries went to get a prescription filled but the pharmacy had no record of plan assignment for them, pharmacists might have filled the prescription and billed a point-of-service contractor selected by CMS to pay and reconcile claims, but they were not required to do so.

The current point-of-service system could be modified to respond to other common problems that arise for dual eligibles at the pharmacy. For example, some duals are assigned to more than one plan. Some are improperly charged higher copayments, even though they are entitled to minimal cost-sharing, because the information in the pharmacy's computer system is incorrect. In a national survey of pharmacists conducted at the end of March 2006, more than half of respondents said they had at least five Part D-related problems each day.[34] When beneficiaries encounter problems at the pharmacy, they may not get the drugs they need, they may be overcharged for drugs they receive, or pharmacists may provide the drugs but incur financial risk themselves. Two surveys of pharmacists indicate that about half reported dispensing prescriptions to Medicare beneficiaries before knowing they would be reimbursed.[35]

The point-of-service system could be made mandatory for use by all pharmacists, and strengthened to allow, on a temporary basis, prescription coverage for all dual eligibles who encounter problems at the pharmacy. For example, once a Medicare beneficiary shows evidence of Medicaid coverage or subsidy enrollment, a prescription could be filled

immediately and billed to the point-of-service contractor. CMS or the point-of-service contractor could then determine how to bill the plans so that neither the beneficiaries nor the pharmacists would be at financial risk, and dual eligibles would have access to their medically necessary drugs. An added advantage to expanding the system would be that the extent and severity of some of the difficulties dual eligibles face could be documented and addressed more easily if one entity were charged with problem solving. Currently, beneficiaries seeking to resolve problems may be advised to contact CMS, SSA, state Medicaid offices, and Part D plans. This situation makes it difficult to develop coordinated systematic responses to problems.

A Source of Confusion:
The Relationship Between Part D Plan Enrollment and the Receipt of Other Medicare Services

Now that beneficiaries must make choices about how they will receive prescription drug benefits as well as other Medicare services, the process associated with evaluating the risks and benefits of any enrollment choice is much more complex.

The Part D choices are not only a source of confusion, but also of unintended changes in coverage for some beneficiaries. Beneficiaries who enroll in a Medicare Advantage Part D plan (MA-PD), for example, may not understand that this also necessitates a switch from fee-for-service coverage for Parts A and B under traditional Medicare to managed care under the private MA-PD plan. Reports explain that insurers offering both stand-alone point-of service and MA-PD plans have aggressively marketed their MA plans.[36] Some beneficiaries may appreciate the opportunity to enroll in an MA plan for all of their Medicare services, such as lower cost-sharing, coordinated care, and other expanded benefits. Others may not be aware, however, that when they choose an MA-PD, they are enrolling in a managed care system that may require them to change health care providers.

Low-income beneficiaries already enrolled in MA managed care plans that have prescription drug components are automatically enrolled in the MA-PD plan, even if their MA-PD has a premium set above the regional low-income benchmark. In that case, a low-income MA enrollee could choose to pay the difference between the MA-PD premium and the low-income subsidy amount, switch plans, or return to traditional Medicare. Those who choose to switch plans rather than to pay the higher premiums experience a disruption in their existing Medicare coverage for Part A and B services since they generally must move to a different network of providers.

In addition, the Medicare Modernization Act of 2003 authorized the creation of Special Needs Plans (SNPs) to provide specialized care through Medicare Advantage plans to certain groups of Medicare beneficiaries: dual eligibles, those with chronic illnesses, or those residing in long-term care facilities. Medicaid managed care plan sponsors can apply for and receive certification to operate Medicare SNPs. Effective January 1, 2006, some Medicare managed care sponsors were permitted to passively enroll their Medicaid dual eligibles into their SNPs to receive their Medicare services. SNPs were required both to inform beneficiaries that they had been passively enrolled into a different type of plan and to offer them the option to disenroll. Some beneficiaries, however, did not understand that their Medicare coverage may have changed even though they did not request it.[37]

STEPS TO IMPROVE THE USE OF FORMULARIES AND UTILIZATION MANAGEMENT TOOLS

Part D plans have broad discretion, within certain statutorily prescribed parameters, to decide which drugs to include in their formularies; the strengths and dosage forms of covered drugs to include; and the types of "utilization management processes" used to control drug costs and usages. Under utilization management, plans may establish different copayments for different drugs: "tiered pricing" distinguishes among preferred drugs, non-preferred drugs, generic drugs, and specialty drugs. Plans may also limit the number of pills or dosage amounts; require that beneficiaries request prior authorization for covered prescription drugs; or require that they try particular medications included in the plan's formulary before those prescribed by the physician ("step therapy"). Some evidence suggests that utilization management techniques have caused delays or otherwise restricted access to prescription medications, including mental health drugs.[38] These blocks have the potential to cause disastrous outcomes for beneficiaries.

All Part D drug plan sponsors must establish a coverage determination process through which a plan enrollee may challenge formulary restrictions or other decisions about drug coverage made by the Part D plan. An exception request—a common type of coverage determination—is the initial step used to ask the plan to cover a drug that is not on the formulary or to request exceptions to rules associated with utilization management. After an unfavorable coverage decision, an enrollee may proceed through five levels of appeal: redetermination by the drug plan; reconsideration by the independent review entity; hearing before an administrative law judge; Medicare Appeals Council review; and finally, appeal to federal court. The processes for requesting coverage determinations and appeals are complex: they require that enrollees act proactively and provide substantial amounts of evidence through all levels of review.

All Medicare beneficiaries are affected by plans' formularies and utilization management rules, but beneficiaries who take multiple prescription drugs are less likely than healthier beneficiaries to find plans with formularies that cover all of their current regimens and therefore are more likely to have to request exceptions. Dually eligible beneficiaries who have been auto-enrolled in plans are among the least healthy beneficiaries and also among those most likely to need an exception to ensure continuous access to all of the drugs that have been prescribed for them. The most vulnerable are among the beneficiaries least able to understand how to pursue an exception request or other coverage determination.

Dramatic changes are needed to current practices to help beneficiaries and those who assist them resolve problems related to the coverage of specific drugs. Concerted efforts to inform beneficiaries about the coverage determination process would be helpful, for example, as would some standardization of the procedures and criteria used in the exceptions and appeals process.

Formularies: New Restrictions for Dual Eligibles

The switch from Medicaid to Medicare Part D coverage may pose difficulties related to plan formularies for dually eligible beneficiaries. One potential problem is that Part D formularies can be considerably more restrictive than Medicaid program formularies. An early report indicated that nearly one-third of dual eligibles were assigned to drug plans that included less than 85 percent of the 178 most commonly used Part D drugs.[39]

Another difficulty is that Part D plans are permitted to change their formularies during a plan year; they are required only to give 60-days notice to those affected by the change. CMS directs plans to maintain coverage for existing users for the remainder of the plan year.[40]

The cost management tools associated with formularies can be problematic. The Alzheimer's Association reports, for example, that three plans—with 8 percent of the market share for total enrollment—required prior authorization for all FDA-approved medications for Alzheimer's disease.[41] (Subsequently, the three plans removed their prior authorization requirements for Alzheimer's drugs.) CMS's guidance allows plans to have prior authorization or other restrictions even for the drugs in the six protected categories, under which plans must cover all or substantially all drugs[42] The plans available for auto-enrollment have a higher percentage of such restrictions than other plans.[43]

Finally, it is important to note that under Part D, most dual eligibles are subject to copayments of between $1.00 and $5.35 (in 2007). Although policymakers usually describe the amount of the copayments as "nominal," monthly expenses can be substantial for low-income individuals who take many medications. And, dual-eligible beneficiaries have lost an important protection that they had under Medicaid: the requirement that pharmacists fill prescriptions even if the beneficiary is unable to make the copayment.

Improve the Coverage Determination Process

Current methods to inform enrollees about exception and appeals processes are not adequate.

To gain access to the drugs they need, plan enrollees must first know they have a right to request an exception or to appeal a coverage decision, and therefore must understand the process. Plans are required to describe coverage determination and appeal rights and procedures in the "welcome package" or evidence-of-coverage documents sent to beneficiaries upon their enrollment, but plans have 30 days from enrollment to provide this information. Thus, new enrollees may have difficulty seeking exceptions or other coverage determinations in the first month of coverage. A requirement for plans to provide information more quickly is necessary.

Generally, beneficiaries first learn they have a coverage problem when their request to fill a prescription is denied at the pharmacy. Plans are required to ensure that pharmacies post or distribute generic notices of the beneficiary's right to contact the plan to seek an exception, but there is little monitoring of pharmacy compliance with this requirement, and the notices themselves are unremarkable. Thus, a beneficiary may leave the pharmacy without knowing they have a course of action to remedy the denial or without knowing what the course of action is. Plan-specific notices describing the denial and subsequent appeal rights could be provided electronically at the pharmacy so that beneficiaries would not have to contact the drug plan for this information before any action can be taken. Within current statutory and regulatory parameters, each plan establishes its own criteria for making coverage determinations. If the criteria used to make coverage and appeals determinations were uniform and widely publicized, beneficiaries and those who assist them would be better able to pursue appeal rights.

The time that beneficiaries must wait for coverage determinations also has been problematic. All Part D plans are required to have a process for making timely coverage determinations: they must issue a written decision within 72 hours for a standard request

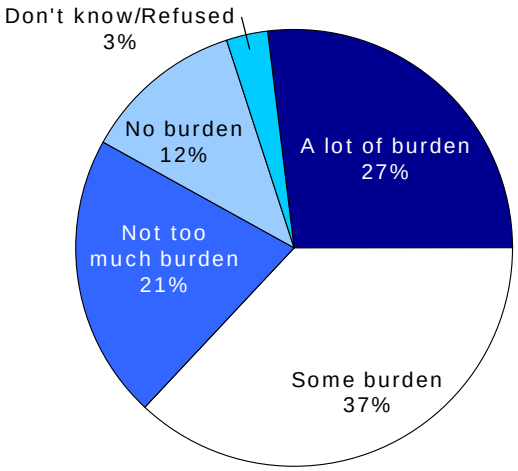
and within 24 hours for an expedited request.[44] CMS, recognizing that plans were not always adhering to these required timeframes—some were making determinations within 24 business hours (3 days) or even 72 business hours (9 days) repeatedly issued clarifying guidance to plans. Reports of delays persist, however, suggesting a need for additional monitoring and enforcement of plan compliance with the requirement.[45]

Use Simpler, More Standard Procedures

Currently, each plan devises its own forms, processes, standards of medical necessity, criteria for reviewing requests for exceptions, and other coverage determinations. Problems with these determinations occurred frequently during the early months of Part D implementation. Beneficiaries and their physicians had difficulty getting information about plan processes and could not get through to appropriate plan representatives by telephone to make coverage requests. In response to this lack of information, CMS posted specific appeals contact information for each Part D plan on its Web site. Still, the burden on many medical practices is enormous, especially considering that in most parts of the country each practice had to be familiar with forms for more than 40 different stand-alone prescription drug plans, plus multiple MA-PDs (Figure 2).[46] Each plan not only has its own form to request an exception; some have different forms for different classes or categories of drugs. Plans that require specific forms do not make them readily available on their Web sites or through their call centers.

Figure 2. Doctors' Assessment of the Part D Administrative Burden

Overall, would you say that helping patients make decisions about the new Medicare drug plans and helping them get their drugs under the plans has placed a lot of burden on you and your staff, some burden, not too much, or no burden at all?



Source: *Kaiser Family Foundation National Survey of Physicians* (Menlo Park, Calif.: Henry J. Kaiser Family Foundation, Sept. 2006); N = 834.

An important first step toward standardization occurred early in 2006, when medical and consumer organizations worked with a health plan trade association to develop a model form for requesting coverage determinations. The form is available on the CMS Web site as well as on the Web sites of many of the largest Part D plans.[47] It is too early to determine how widespread the use of the form is, but a recent survey of medical directors in long-term care facilities showed that only 18 percent said the majority of drug plans they deal with are using the common form.[48] While use of the form is voluntary for the plans, CMS has directed that plans must accept any written request (including the standard form) for an exception or other coverage determination.

More standardization of the process and criteria plans use for exceptions and appeals would be helpful. At the pharmacy, the most logical and efficient approach from the perspective of consumers would be to treat the denial of coverage at the pharmacy as the coverage determination, and then to give beneficiaries standard instructions regarding the next steps in the appeals process. For physicians, the process could be improved considerably if a uniform definition of medical necessity and the standards for proving the need for a particular medication were articulated. Currently, the amount and type of supporting documentation requested from physicians by some drug plans is problematic. In addition to the supporting statement, doctors have been asked to submit all clinical records for the enrollee. Plans also have required that evidence from peer-reviewed medical journals be submitted. It is important to note that Medicare does not compensate physicians for the time spent in seeking or supporting an exception request. And, if changes in drug regimens do occur because of formulary restrictions, Medicare may have to pay for several office visits to monitor the efficacy of the new drug for the beneficiary. In a survey of medical directors working in long-term care facilities, more than half (55 percent) reported frequent problems with requests for exceptions for drugs. Despite language in the statute indicating that physicians' statements are appropriate support for formulary exceptions and language in guidance giving such statements "great weight," the Part D appeal regulations explicitly direct that physicians' opinions do not control determinations about requests for exceptions.[49] As a result, financial rather than medical considerations may be the basis for changes in treatments that have been working effectively for many years.

PART D AND LONG-TERM SERVICES AND SUPPORTS

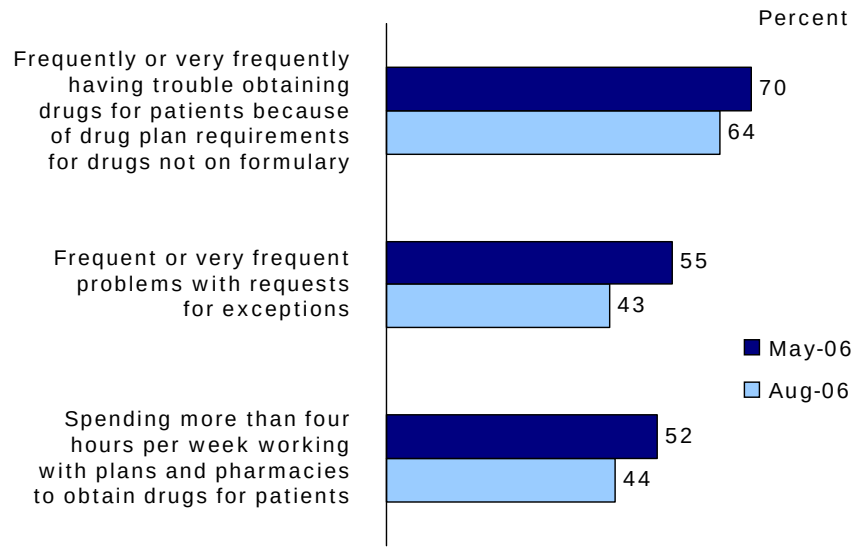
Advocates, the nursing home industry, and the long-term care pharmacy industry are watching to determine how Part D is affecting Medicare beneficiaries who need long-term services and supports.

Ease the Process to Get Appropriate Drugs to Nursing Home Residents

Physicians and pharmacists who provide care and services to nursing home residents report that drugs on plan formularies are not always appropriate for the frail, disabled, and debilitated nursing home population. Physicians report problems with formulary drugs that are frequently inappropriate for their patients, and CMS guidance recommends that these drugs not be used for nursing home residents at all or only with great caution.[50] Some physicians report that prescribing any medication other than a generic drug meets with plan resistance. Residents whose complex drug regimens have been carefully adjusted over the years face tremendous problems with formulary limitations. Almost one-quarter of physicians polled who provide long-term care reported problems obtaining drugs for patients with Alzheimer's disease.[51]

Dual-eligible beneficiaries, who comprise a large portion of nursing home residents, face additional difficulties. Those who do not choose a plan are automatically enrolled, but random assignment to plans does not take into account whether a plan covers a beneficiary's prescriptions in its formulary or includes the facility's pharmacy in its network. As a consequence, the long-term care pharmacy that serves their nursing facility may not be participating in the Part D plans to which some residents are assigned. Surveys of physicians working in the area of long-term care show that although some improvement has occurred over time, many have significant difficulty obtaining drugs for their patients (Figure 3). Many plans require physicians to call plans personally to support exceptions requests; physicians spend an average of 25 to 45 minutes on each call.[52] Physicians are unlikely to maintain these levels of effort indefinitely.

Figure 3. Long-Term Care Physicians' Experience with Part D



Source: American Medical Directors Association Survey of Long-Term Care Physicians, conducted May 2006 (N = 441) and Aug. 2006 (N = 237).

Choosing Plans:
A Particular Problem for Beneficiaries with Cognitive Impairments

Among Medicare beneficiaries who receive long-term care services, the proportion with cognitive impairments is substantial.[53] Many of these beneficiaries are unable to express concerns about the quality of care they receive or the financial arrangements that govern their care. Like all dually eligible beneficiaries, nursing home residents are entitled to change Part D plans at any time, but those with cognitive impairments are unable to make these decisions themselves, and thus cannot choose a plan initially or disenroll from a plan that is not covering all their drugs and then choose a new plan. Furthermore, most nursing home residents have not been adjudicated incompetent and do not have guardians who can act on their behalf. Although many state laws authorize surrogate decision-making related to health care, Part D is a new benefit, and because the issue is not addressed in statute or regulation, it is unclear whether choosing a plan is a health care decision or a financial insurance decision. This problem makes applying state law difficult. Federal law should be clarified to allow family members to assist beneficiaries with enrolling, disenrolling, and pursuing appeals, even if they do not have an official appointment of representative authorization from the beneficiary.

Extend Protections to All Beneficiaries Needing Long-Term Services

The provision of Medicaid-financed long-term services in community-based settings rather than in nursing facilities or other institutions has been promoted by states and the federal government and is preferred by many beneficiaries. Much existing public policy favors offering this choice, yet the Medicare Part D copayment rules may make the option of living in the community difficult for many dually eligible people.

Under Medicaid rules, beneficiaries in nursing facilities or other institutions and in home and community-based settings—including assisted living and board-and-care facilities—can keep only a small amount of money, generally $35 to $50 per month, for personal needs such as clothing or toiletries.[54] Despite their lack of available income, beneficiaries in the community have cost-sharing obligations under Part D for their drugs.[55] They must make copayments for prescription drugs that are covered by their Part D plan. In addition, they must pay for any prescription drugs not covered by their plan's formulary (unless they successfully win an exception or appeal), for prescription drugs that are excluded from coverage under Part D by the Medicare Modernization Act, and for over-the-counter drugs. They also may be required to pay full price for a non-formulary drug while pursuing an exception.

Dually eligible residents of nursing homes and other institutions, however, are not required to make any copayments under Part D.[56] Moreover, dual eligibles in nursing homes do not have to pay for over-the-counter drugs,[57] and the federal Nursing Home Reform Law requires nursing facilities to provide them with all drugs that are required by their physicians, even if there is no source of payment for those drugs.[58] CMS guidance directs plans to provide a supply of non-formulary drugs to residents of institutions pending the outcome of a request for a formulary exception.[59,60]

Depending on their drug needs and the coverage provided by their Part D plans, beneficiaries in community-based settings may have significant monthly drug costs that they cannot afford. This expense could be one factor that influences a beneficiary's choice to move to a nursing facility rather than stay in the community. Eliminating the disparity in copayments by applying the nursing home copayment rule to individuals receiving community-based long-term care services would assist in alleviating this problem.

A source of assistance for dual eligibles in nursing homes and in certain community-based settings to pay for copayments as well as for non-covered drugs is Medicaid's incurred medical expense deduction. This required deduction allows a beneficiary to deduct such expenses from his or her income before paying most of the

remainder of the income to the provider of services. This benefit is not well publicized, however, and having good information about this benefit and how to use it in their states would enhance beneficiaries' lives.[61]

EFFORTS TO IMPROVE PROGRAM QUALITY

Experience in 2006 suggests that certain steps could be taken to ensure that the Part D program operates more effectively. As noted above, more monitoring on the part of CMS is needed, as is government-supported strengthening of electronic communication systems. In addition, efforts are needed to provide program information in new ways and to ensure that beneficiary counselors continue to be available.

Strengthen Electronic Communication

A number of entities are involved in the administration of the Part D program: CMS administers the Medicare program and has overall responsibility for Part D; SSA and state Medicaid offices have primary responsibility for enrolling applicants into the low-income subsidy; Part D plans provide the benefits; and pharmacies fill prescriptions. CMS has established systems to convey information electronically about beneficiaries' plan affiliation and subsidy status, but difficulties arise when the information in the system is incorrect, not current, or when its transmission is infrequent.

Pharmacists are accustomed to working with computer systems that function in "real-time," and the slower Part D system can be problematic. For example, dual eligibles may switch plans anytime during a month and new coverage should be effective the first of the following month. If the electronic switch has not been fully processed by then, however, beneficiaries may be unable to obtain medication from their new plan when they go to the pharmacy.

In addition, information about the subsidy status of the beneficiary is often not available to the pharmacist in a timely manner. As a result, dual eligibles are incorrectly charged copayments applicable to the general Medicare population[62] that are unaffordable to them.[63] A logical solution would be to develop a single system that allows information about plan enrollments, disenrollments, and subsidy status to appear in the computer system nationwide within minutes of a change rather than after days, weeks, or months.

Provide Program Information in New Ways

Some beneficiaries have had difficulty obtaining accurate, detailed information about the Part D program in a timely manner. Notices sent to beneficiaries by Part D plans have also been a source of confusion, particularly when generic notices—such as notices about

required copayments—are sent to all beneficiaries, but may apply only to some of them. Beneficiaries seek information from physicians and pharmacists, who traditionally are trusted sources of information, but these professionals often do not have access to all of the information they need to help. The medicare.gov Web site is remarkable for the amount of material presented, but it is difficult to use. Also, many beneficiaries do not have access to the Internet or do not know how to use it.[64,65]

The provision of more general information on paper about the program, the plans, and how to choose, enroll in, and use a plan would be helpful. Similarly, beneficiaries and those who assist them need information about applying for and using the low-income subsidy and instructions about how to request a coverage determination or file an appeal. Easy-to-read written materials in multiple languages are also badly needed. Notices and information should be sent regularly to beneficiaries at a literacy level appropriate to them and in a language they can read. This provision may require additional resources for the development and enforcement of standards regarding literacy level and translations.

The national toll-free Medicare number (1-800-MEDICARE) is available for answering questions, but accessibility continues to be a major problem and counselors do not always provide accurate information.[66] One possible means of expanding and improving Medicare's customer assistance, information, and problem-solving capacity is to train personnel in various areas of expertise so that calls from beneficiaries, plans, pharmacies, and advocates, all of whom have different issues and needs, can be answered effectively. In addition, staffing levels should be appropriate, and the competency of all operators or counselors should be evaluated before they serve customers. CMS should use its enforcement authority to monitor how plans provide customer information and to sanction plans that do not comply with appropriate standards. In addition, Congress should monitor and evaluate CMS to ensure the quality of its materials, customer service, and information functions.

Ensure Support for Counseling

Some of the issues that confused beneficiaries at the initial implementation of Part D have been addressed; others remain unresolved. The need for more and ongoing assistance is anticipated as Part D plans enter and exit the market for the second year of the program; as they make changes to their formularies, cost-sharing requirements, and other policies and procedures; and as recertification for the LIS is required.

By necessity, much of the counseling and problem-solving to date has occurred on a one-to-one basis, but this is a difficult level of effort to sustain. State Pharmaceutical

Assistance Programs, which existed in many states prior to the Part D benefit and are still active in about 20 states, have been helpful in counseling beneficiaries and, in some instances, in enrolling them in plans to coordinate with state benefits.[67] The State Health Insurance Assistance Programs (SHIPs) in each state have been funded to counsel all Medicare beneficiaries but have been overwhelmed by the demand for assistance. Federal funding for the SHIP program increased from $12.5 million in 2003 to $31.7 million in 2005, and in both 2006 and 2007 to about $30 million. This amount represents about $0.70 per Medicare beneficiary; the SHIP community estimates that $1 per beneficiary is needed.[68] One-on-one counseling is often essential but not always available.[69] Populations with limited-English proficiency and disabilities have special needs, and funding for community-based organizations to provide one-on-one counseling to these groups is needed.

CONCLUSION

The Medicare Part D Program provides valuable new prescription drug assistance to millions of beneficiaries. Satisfaction among enrollees is reportedly high, yet a substantial portion of eligible beneficiaries is not enrolled. More than 3 million are low-income beneficiaries who qualify for programs subsidies. This high figure suggests that efforts to publicize the subsidies, simplify enrollment, and assist beneficiaries are needed.

For those who are enrolled, program changes to smooth transitions from Medicaid to Medicare and to make the rules associated with obtaining prescription drugs simpler and more explicit would be helpful. After a year of experience, program refinements such as strengthening electronic data transfers, monitoring plan operations more closely, and developing more effective ways of communicating information would help ensure program quality for all beneficiaries, and particularly for the frailest, sickest, and most vulnerable. These changes should be made to enhance the performance of Medicare Part D and increase its usefulness in accomplishing the purpose for which it was intended: to provide access to needed health care for the elderly and disabled.

Recommendations to Strengthen Part D Program Areas

The Low-Income Subsidy

- Eliminate or amend the resource test
- Provide enrollment encouragement and assistance
- Monitor redeeming and redetermination

Transition from Medicaid to Medicare

- Use available information in making plan assignments
- Simplify the transition process by extending the supply of non-formulary drugs
- Expand the "point-of-service" system

The Use of Formularies and Utilization Management Tools

- Improve the coverage determination process
- Use simpler, more standard procedures

Part D and Long-Term Services and Supports

- Ease the process to get appropriate drugs to nursing home residents
- Extend protections for nursing home residents to individuals in the community

Program Quality

- Strengthen electronic communication
- Provide program information in new ways
- Ensure support for counseling

NOTES

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[13] See 20 C.F.R. § 418.3125 (2005).

[14] L. Summer and L. Thompson, *How Asset Tests Block Low-Income Medicare Beneficiaries from Needed Benefits* (New York: The Commonwealth Fund, May 2004).

[15] Because of CMS and SSA outreach efforts focused on applying for LIS through SSA as well as to states' lack of interest in processing LIS applications because they are paid only fifty cents on the dollar for their costs, it is likely that few beneficiaries know that their LIS applications can be processed at state Medicaid offices.

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[17] See 42 U.S.C. § 1395 w-101(b)(1)(C). Qualifying plans have premiums at or below a regional benchmark that is defined as a weighted average of premiums for "basic" plans for that region. People in Medicare Advantage managed care plans are assigned to their sponsor's Part D plan, if one is available.

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[27] Ibid.

[28] Kaiser Family Foundation, *National Survey of Pharmacists: Findings on Medicare Part D* (Menlo Park, Calif.: Henry J. Kaiser Family Foundation, Sept. 2006). Available at: http://www.kff.org/kaiserpolls/7555.cfm. In chart 20, 73 percent of independent pharmacists reported dispensing drugs under Part D without knowing for certain that they would be reimbursed.

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[31] V. Smith, K. Gifford, E. Ellis et al., *Low Medicaid Spending Growth amid Rebounding State Revenues: Results from a 50-State Medicaid Budget Survey* (Menlo Park, Calif.: Henry J. Kaiser Family Foundation, Oct. 2006); J. Hoadley, *Medicare's New Adventure: The Part D Drug Benefit* (New York: The Commonwealth Fund, Mar. 2006).

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[42] CMS requires, through guidance, coverage of all or substantially all of the drugs in six categories considered especially important to this population: antidepressants, antipsychotics, anticonvulsants, antiretroviral, antineoplastics, and immunosuppressants.

[43] "Coverage and Access Restrictions in the Six Protected Classes: Review of Formulary in Medicare Prescription Drug Plans," presented at MAPRx Meeting, June 28, 2006, Washington, D.C.

[44] 42 C.F.R. § 423.568 and 423.570 (2005) For a more detailed description of the Medicare Part D exceptions and appeals process, see NSCLC, *Part D Exceptions,* Aug. 2006.

[45] In a March 17, 2006, letter to drug plan sponsors about the transition process, CMS included an attachment entitled "Important Reminders About Part D Coverage Determinations and Appeals." The document specifically included the time periods and a reminder to send claims that cannot be resolved in a timely way to the IRE. See also letters from Gary Bailey, "Next Steps on Formulary Transition Policies," March 17, 2006. Another letter from Gary Bailey issued two weeks later, "Critical Steps as Transition Period Ends," also discussed the need to comply with the time periods, March 31, 2006.

[46] It is difficult to determine the actual number of Medicare Advantage plans operating in any given region, since plans are reported on a county-by-county basis, so that what is essentially the same plan appears as a different plan in each county in a state. A list of Part D plans available as of Sept. 30, 2005, shows a range of zero in Alaska and Vermont to 257 in Florida.

[47] The form is available at: http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.

[48] American Medical Directors Association, "Long-Term Care Physicians Experience Difficulties in Prescribing Selected Drugs for Patients in Medicare Part D" (news release) (Columbia, Md.: AMDA, June 1, 2006). Available at: http://www.amda.com/news/releases/2006/060601_medicare_part_d.cfm.

[49] See 42 U.S.C. § 1395w-104(g)(2); CMS Prescription Drug Benefit Manual, Ch. 18 §30.2.1.; 42 C.F.R. § 423.578(f).

[50] Daniel Haimowitz, American Medical Directors Association, spoke about the generic drug issue at a forum, "Impact of the Medicare Modernization Act on Long-Term Care," sponsored by the Health Policy Institute of the University of the Sciences, May 1, 2006.

[51] AMDA, "Long-Term Care Physicians," 2006.

[52] American Medical Directors Association, "Long Term Care Physicians Still Experience Difficulties in Prescribing Selected Drugs for Patients in Medicare Part D" (news release) (Washington, D.C.: AMDA, Oct. 12, 2006). Available at: http://www.amda.com/news/releases/2006/101206.cfm.

[53] American Health Care Association, CMS On-line Survey, Certification and Reporting: Medical Condition: Mental Status. Reports 46.5 percent with diagnosis of dementia, 20.1 percent with psychiatric diagnosis, 46.8 percent with depression, 2.8 percent with mental retardation, and 30 percent with behavioral symptoms, Dec. 2005. Available at www.ahca.org/research/oscar/rpt_MC_mental_status_200512.pdf.

[54] Like nursing home residents, beneficiaries under home and community-based waivers are subject to Medicaid's post-eligibility rules and must contribute their income to the cost of their care. See 42 C.F.R. §435.726(c)(4)(i), (ii) (individuals receiving home and community-based services under a waiver in SSI states), §435.735(c)(4)(i), (ii) (individuals receiving home and community-based services under a waiver in states using more restrictive requirements than SSI) and §435.832(c)(4)(i), (ii) (medically needy).

[55] 42 U.S.C. § 1395w-114(a)(1)(D). In the final regulations [70 Fed. Reg. 4193, 4236 (Jan. 28, 2005)], CMS declined to expand the definition of institutionalized individual to include beneficiaries in home or other congregate living or home settings such as assisted living facilities. Given the statutory definition with which CMS was working, it may be that congressional action is needed to eliminate cost-sharing obligations for such individuals.

[56] See 42 U.S.C.A. § 1395w-114(a)(1)(D)(i) (West Supp. 2006).

[57] See 42 C.F.R. § 483.10(c)(8)(i)(E) (2005).

[58] 42 U.S.C.A. § 1395i-3(a)-(h) (Medicare), 42 U.S.C. § 1396r(a)-(h) (Medicaid) (West Supp. 2006). See also 56 Fed. Reg. 48850 (Sept. 26, 1991) (Preamble to Final Requirements of Participation for Skilled Nursing Facilities and Nursing Facilities).

[59] See http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/EmerTLCFill.pdf. This provision applies to all residents of long-term care facilities, not only to dually eligible residents and not only to residents of nursing facilities.

[60] Rules for copayments also adversely affect nursing home residents though to a lesser degree than they affect those in other settings. Although a dually eligible resident is exempt from copayments, the exemption does not begin until he or she has been institutionalized for a full calendar month as a Medicaid beneficiary. In practice, the gap lasts more than a month, since a beneficiary more often than not will move into a nursing home as a Medicaid beneficiary on a day other than the first day of a month.

[61] See 42 U.S.C.A. § 1396a(r)(1) (2005 Supp.).

[62] Centers for Medicare and Medicaid Services, "Updated Guidance—Changes to Effective Date and PDP Notice Requirements for Auto-Enrollment and Facilitated Enrollment" (Washington, D.C.: CMS, Mar. 17, 2006). Available at: http://www.ilr.cornell.edu/EDI/publications/FE_guidance_memo_PDP_03-17-06_FINAL.pdf.

[63] The enrollment, disenrollment, and subsidy problems have been so severe that a lawsuit was filed on behalf of the dual eligibles to force CMS to improve the auto-enrollment and computer system. See http://www.nsclc.org/areas/medicare-part-d/area_folder.2006-09-28.5758698482/area_folder.2006-10-12.2022247391.

[64] Aronovitz, *Quality of CMS Communications,* 2006.

[65] V. Rideout, T. Neuman, M. Kitchman et al., *E-Health and the Elderly: How Seniors Use the Internet for Health Information* (Menlo Park, Calif.: Henry J. Kaiser Family Foundation, Jan. 2005), available at: http://www.kff.org/entmedia/upload/e-Health-and-the-Elderly-How-Seniors-Use-the-Internet-for-Health-Information-Key-Findings-From-a-National-Survey-of-Older-Americans-Survey-Report.pdf; S. Kaye, *Disability and the Digital Divide* (San Francisco: University of California, San Francisco, Disability Statistics Center, July 2000), available at: http://dsc.ucsf.edu/publication.php?pub_id=6.

[66] Aronovitz, *Quality of CMS Communications,* 2006.

[67] National Conference of State Legislatures, *State Pharmaceutical Assistance Programs in 2006: Helping to Make Medicare Part D Easier and More Affordable* (Washington, D.C.: NCSL, Oct. 18, 2006). Available at: http://www.ncsl.org/programs/health/SPAPCoordination.htm#State.

[68] Health Assistance Partnership, "State Health Insurance Assistance Programs: A Critical Resource for Medicare Beneficiaries" (Washington, D.C.: HAP, May 2006). Available at: http://www.healthassistancepartnership.org/assets/pdfs/HAP-SHIP-Issue-Brief-2006-Final-May-2006-1.pdf.

[69] Medicare Payment Advisory Commission, *Report to the Congress: Increasing the Value of Medicare* (Washington, D.C.: MedPAC, June 2006). Available at: http://www.medpac.gov/publications/congressional_reports/Jun06_EntireReport.pdf.

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