



MEDICARE PART D AFTER YEAR ONE: A REVIEW OF PROBLEMS, AND RECOMMENDATIONS FOR CHANGE

January 16, 2007

EXECUTIVE SUMMARY

After one year's experience with Medicare Part D, many people remain confused and frustrated by the complexity and limitations of the benefit. Problems are difficult to resolve because of system failures, complicated data-sharing requirements among multiple entities, lack of useful and standardized information about plan benefits and appeal processes, and regulatory limitations that are more stringent than required by law.

The beneficiary stories in this report are illustrative of the many beneficiaries who are experiencing problems and high costs due, in large part, to the lack of uniformity in Medicare Part D. The stories focus on particular aspects of Part D implementation – the failure of systems to ensure that low-income beneficiaries are enrolled in plans and receive their subsidies, the lack of useful information about benefit limitations to help beneficiaries plan, the failure of the system for withholding plan premiums from beneficiaries' Social Security checks, and the lack of uniform policies and procedures for seeking exceptions to formulary limitations.

Reflection on the issues underlying these problems confirms that beneficiaries would be better off with a redesigned benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.

Accordingly, the Center for Medicare Advocacy continues to call for systemic changes to Part D. Our key recommendations include the following:

Recommendations for Congress:

1. Congress should redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.
2. Congress should eliminate the Donut Hole. If the Donut Hole is not eliminated, Congress should, at a minimum, authorize payments by AIDS Drug Assistance Programs (ADAPs) programs and pharmaceutical assistance program (PAPs) to count towards the beneficiary out-of-pocket spending limit.

3. Congress should require Part D plans to give deference to the opinion of the beneficiary's attending physician when making coverage decisions and should require CMS to delete the provision to the contrary in its regulations [42 CFR§ 423.578(f)].
4. Congress should authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act.
5. Congress should hold oversight hearings on the implementation of Part D. The hearings should include an inquiry into the special problems of dually eligible beneficiaries, the withholding of premiums by plans and Social Security, and CMS's role in setting and enforcing standards for plan participation.
6. Congress should require CMS to expeditiously establish a full system of real time data-sharing among all entities involved in Part D. Congress should require CMS to report on its strategies to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS.

Recommendations for the Centers for Medicare & Medicaid Services (CMS)

1. CMS should create a real time data-sharing system among all entities involved in Part D, and develop mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.
2. CMS should expand its point of service (POS) system to make its coverage available at the pharmacy for all dually eligible persons who experience plan enrollment and related drug dispensing problems at the pharmacy. Further, CMS should require pharmacies to use the POS system, and hold pharmacies harmless for good faith billings to the POS that turn out to be incorrect.
3. CMS and Part D plans should be required to provide beneficiaries with clear and accurate information about Part D, individual plan offerings, and in particular, about the Donut Hole coverage gap. This information should include the following:
 - Materials from CMS and the enrollee's plan that explain how the initial coverage limitation and beneficiary out-of-pocket expenses, including Donut Hole payments, are calculated should be mailed to beneficiaries;
 - Monthly statements that clearly indicate the total amount of payments that have been made that count towards the individual's initial coverage limit and beneficiary out-of-pocket responsibilities should be mailed to beneficiaries; and
 - Monthly statements that indicate, after the initial coverage limit has been reached, all costs that continue to count towards the out-of-pocket limit in the Donut Hole and how much more is needed to reach catastrophic coverage should be mailed to beneficiaries .

4. CMS should require plans to provide a written coverage determination electronically at the pharmacy whenever a drug is not covered. The written coverage determination must explain why the plan will not pay for a drug, describe beneficiary appeal rights, and explain how to request the next level of review.
5. CMS should ensure that Part D plans comply with required appeals and grievance processes, that plan call centers respond appropriately to beneficiaries, and that Medicare “customer service” representatives provide accurate information and keep track of beneficiary complaints.
6. CMS should exercise its enforcement authority to take actions against Part D plans that do not provide adequate notice, fail to meet the regulatory time frames for deciding a coverage determination or an appeal, or fail to train their call center staff adequately.

INTRODUCTION

The Center for Medicare Advocacy has assisted thousands of Medicare beneficiaries and their helpers to understand and utilize the Part D system, plan options, and rules. In our conversations with Medicare beneficiaries, their advocates, and policy-makers, we hear repeatedly about beneficiaries having insufficient information to make sound decisions about which plan to choose, to understand what should be covered, and to know how they will fare during Part D’s various coverage gaps. They also report difficulty obtaining exceptions for drugs not on a plan’s formulary, for drugs with quantity limits, and for the off-label use of certain drugs. Similarly, we hear many complaints that the exceptions process is both complicated and vague. Beneficiaries who are dually eligible for Medicare and Medicaid are too often unable to obtain their medications due in large part to data-sharing problems among states, the Centers for Medicare & Medicaid Services (CMS), and Part D plans.

As we noted in our Six-Month Report (July 19, 2006), CMS, the agency that administers Medicare, continues to tout Part D as a resounding success, while characterizing what are persistent and systemic issues as small glitches in the system. Our experience continues to show otherwise. Systemic problems identified at the beginning of 2006 continued, and new problems developed during the course of the year. This report highlights some of the most glaring continuing problems:

- As currently designed, the Part D program is immensely complicated. The program’s complexities affect the ability of beneficiaries to understand the program, choose plans, pay premiums, benefit appropriately from the low-income subsidy, and utilize the exceptions and appeals process.
- CMS’s administration of the Low-Income Subsidy (LIS) lacks clarity and uniformity so that the subsidy too often fails to reach eligible beneficiaries.
- Beneficiaries do not have adequate information to allow them to make sound Part D plan choices or to properly prepare for the gap in coverage of necessary drugs during the “Donut Hole.”
- The Part D exceptions and appeals process is too complex and too varied from plan to plan to be adequately accessible to Medicare beneficiaries. Further, the standards for appeals are too vague and do not give adequate credence to the opinion of beneficiaries’ attending physicians.

PART D IS IMMENSELY COMPLICATED. THIS COMPLEXITY AFFECTS ALL ASPECTS OF THE PROGRAM.

1. The Complexity Of Part D Causes Special Problems For Low-Income Beneficiaries

One of the major changes made by Part D is the requirement that beneficiaries who are eligible for both Medicare and Medicaid (dually eligible beneficiaries) get their prescription drugs through Medicare Part D. On January 1, 2006, these people lost their eligibility for prescription drug coverage under Medicaid. Further, Medicaid beneficiaries who become newly eligible for Medicare lose their Medicaid drug coverage when their Medicare eligibility begins, even if they are not enrolled in a Medicare prescription drug plan. Such beneficiaries may experience drug coverage gaps when they are first eligible for Medicare due to time lags in the transmission of information about their new dual status, which must flow from the state to CMS. This change in drug coverage for low-income beneficiaries was the source of some of the most serious and significant problems when Part D began in 2006. Problems with Part D drug coverage for dually eligible people persisted throughout the year. For example:

Mrs. S, an SSI recipient who had been on MassHealth (Massachusetts Medicaid) and had a number of health problems, including bipolar disorder and diabetes, turned 65 on September 17th and became eligible for Medicare effective September 1, 2006. When she went to the pharmacy in early September, nine months after Part D began, she learned, when the pharmacist tried to bill MassHealth, that she no longer had Medicaid prescription drug coverage. The pharmacist was told that Medicare's records showed that the woman was in a Part D plan. However when he tried to bill that plan, he was unable to do so. Plan officials told both the pharmacist and the client's social worker that they had no record of her. The pharmacist then tried to bill Wellpoint/Anthem, the "Point of Service" (POS) option for dual eligibles who do not have a drug plan, but was unable to do so because Medicare records showed that she was already enrolled in a plan. She left the pharmacy without her medications.

Although CMS automatically enrolls dual-eligible beneficiaries into plans, effective the first day of the month in which they become dually eligible for both Medicare and Medicaid if they have not chosen a plan themselves, the enrollment may not, in fact, have been effectuated by the time they lose Medicaid coverage. Although they are entitled to reimbursement for out-of-pocket costs above the level of their subsidized co-payments, their low-income status may make it impossible for them to actually pay out-of-pocket. Those beneficiaries who choose a plan, rather than accept auto-enrollment, must affirmatively request through their plan that their enrollment be retroactive to the date they became dually eligible. The plan must submit the request to CMS.

As Mrs. S's story indicates, CMS has a point of service (POS) system that allows a newly dually eligible beneficiary for whom plan enrollment information is not available to receive drug coverage at the pharmacy (the "point of service") upon a showing of proof of Medicare and Medicaid enrollment. However, this system is not available to other dually eligible persons who experience difficulties at the pharmacy, including those for whom CMS's records show enrollment in a specific plan. Moreover, many pharmacists are unfamiliar with the POS system and, even if they know about the system, they are not obligated to use it. Further, if pharmacists use the POS system in error, the pharmacy is liable for the difference between the billed amount and the full cost-sharing due. Ironically, because Mrs. S was already enrolled in a plan that did

not acknowledge her enrollment, the POS option did not work for her and she was worse off than if she had not been enrolled in a Part D plan at all.

A. Information About Subsidy Status Is Also Often Delayed In Its Transmission To The Plan And The Pharmacy

Although dually eligible persons are entitled by law to change plans at any time, they do so at their peril. Considerable confusion often occurs when plan changes are made and it may be difficult to understand which plan is responsible to pay for a drug during a plan-change transition. For example:

Mr. B, a Medicare beneficiary who resides in the dementia unit in a nursing home, was enrolled by his daughter into a Part D drug plan in January 2006. In April 2006 he became eligible for Pennsylvania Medicaid.

It took five months, and 15+ phone calls to Medicare, the regional CMS office, Pennsylvania Department of Welfare, the local Medicaid office, the Part D plan and the nursing home just to get Medicare to update the beneficiary's status to dual-eligible so that he no longer had to pay monthly drug premiums, co-payments, or the full cost of his drugs. The Pennsylvania Department of Welfare had the wrong birth date for the beneficiary in its records, listed him as not being on Medicare at all, and delayed sending the updated information to the Medicare database. The drug plan also could not update its information until Medicare had updated its information. The nursing home kept reminding the daughter that her father's drug bills were going unpaid.

Medicare beneficiaries becoming newly eligible for Medicaid experience delays in getting access to their low-income subsidy. Data are transmitted by the states monthly; a beneficiary whose dual status is determined the day after the monthly transmission will not appear as a dual-eligible until the following month. Mr. B's story illustrates the complexities of the data-sharing that is required to ensure that dual-eligible beneficiaries do not experience coverage gaps or gaps in their entitlement to lower cost-sharing when they become dually eligible. It also illustrates the complexity of resolving such problems, because so many entities are involved and each may be required to take some action that depends on the prior actions of another agency.

B. Re-determinations Of Eligibility For Low-Income Subsidy Are Made Through Multiple Mechanisms, Leading to Confusion and Errors

Low-income beneficiaries must re-qualify for the Part D low-income subsidy (LIS) each year. Since several paths exist for re-qualification, the process is confusing, especially for those whose circumstances fluctuate over the course of a year. Medicare beneficiaries who are also enrolled in Medicaid, a Medicare Savings Program, or SSI are "deemed eligible" for LIS. If individuals were on the rolls in one of these programs in July of 2006, they were to be "re-deemed" eligible for the subsidy for 2007. As Mrs. M's story indicates, however, plans do not always have correct information about beneficiaries' subsidy-eligibility status:

Mrs. M, a dually eligible resident of Virginia who is deemed eligible for the low-income subsidy (LIS), was told that she needed to meet the Part D \$265

deductible when she went to get a prescription on January 2, 2007, although people entitled to the LIS do not have a deductible. The woman had no changes in her income, assets, or program eligibility for SSI, Medicaid, or Medicare. Her Medicaid eligibility worker called her drug plan and was told the woman had lost her low-income subsidy eligibility.

In December 2006, CMS sent a memorandum to Part D plans explaining that they must use the best available data to reconcile status when a beneficiary believes he or she is still eligible for the subsidy. The beneficiary may present proof of eligibility, such as a Medicaid card, at the pharmacy and the plan should follow up to collect the evidence. In Mrs. M's situation, however, the plan failed to explain to the pharmacist that the beneficiary could present documentation of her Medicaid eligibility at the pharmacy in order to continue receiving the subsidy, and her medications, until the issue was resolved.

Another example:

Mr. and Mrs. Y have developmental disabilities and qualified for Missouri Medicaid for a portion of 2005 after they "spent down" their excess income to meet medical expenses. Thus, they were deemed eligible for the full low-income subsidy in 2006. Because they allegedly had not met their "spend-down" amount in the second half of 2006, however, they were not deemed eligible for the low-income subsidy for 2007. The couple qualifies for a partial subsidy based on income, and so, in contrast to their experience in 2006, they will have to pay a deductible and premium for their drug coverage in 2007. They will also have to pay more for each prescription.

An advocate who was assisting the couple in choosing new drug coverage at the end of December 2006 discovered that the couple had hospital and medical bills that should have been sufficient to establish that they had met their "spend-down amount" (payment toward medical expenses, recognized by Medicaid, as reducing the applicant's income for purposes of qualifying for Medicaid) in October 2006. Had they submitted the medical bills to the state Medicaid agency, they would have been eligible for Medicaid and deemed eligible for LIS for all of 2007. Because they did not submit the medical documents on time, they will have to pay premiums and cost-sharing until their Medicaid is established retroactively. They will then be deemed eligible for full LIS retroactively, and they and their advocate will have to take steps to seek reimbursement for the premiums and other expenses they paid until information about their LIS-subsidy level is shared with their drug plan.

Individuals who were not on the Medicaid rolls at the time CMS made deemed status decisions were sent letters telling them that they were losing their subsidy because of the loss of their other benefit. The letter included an application to be mailed to the Social Security Administration. However, if the individual later regains eligibility for the other benefit, he or she will be re-deemed for the LIS, without further consideration of his or her SSA application. While this is a desirable outcome, beneficiaries are too often confused by the array of letters they receive regarding their changing status. Moreover, delays in the transmission of subsidy information between states, SSA, CMS, and plans may result in incorrect LIS status information being available at the pharmacy when a beneficiary arrives in 2007. As described above, this can result

in low-income people paying more than they should – and sometimes failing to obtain their medications.

When a Medicaid beneficiary loses eligibility for Medicaid benefits, states have an obligation under Medicaid law to determine if that person is eligible under another category of the state's program. For example, someone losing Medicaid eligibility might, nonetheless, still be eligible for a Medicare Savings Program, since these income and resource limits are higher than Medicaid in most states. If states routinely undertook these new determinations of eligibility for other Medicaid benefits before terminating people from the program, fewer LIS recipients would find themselves in the limbo of not knowing about their LIS status. Similarly, even for those individuals no longer eligible for any benefits under the state Medicaid program, the state or the Social Security Administration (SSA), whose income and resource limits are higher than those of most states' Medicaid programs, could undertake independently to determine their eligibility for the LIS.

SSA is required by law to redetermine eligibility of those individuals who applied for LIS through SSA within the first year after their initial enrollment. SSA used a largely "passive" redetermination process for 2007. It sent letters to beneficiaries who qualified for the LIS in 2006 asking them to contact SSA if their circumstances had changed. If the individual's circumstances had not changed, the beneficiary was not required to take any action. If they had, the process continued. Little information is available at this time on the effectiveness of this system.

After the first redetermination, the Commissioner of SSA has discretion to undertake redeterminations as necessary. Since most low-income Medicare beneficiaries do not have significant changes in income and resources, the Commissioner could exercise his discretion to minimize redeterminations.

Recommendations

Congress should hold oversight hearings on the implementation of Part D. The hearings should include an inquiry into the special problems of dually eligible beneficiaries and CMS's role in setting and enforcing standards for plan participation.

Congress should require CMS to create a plan to move expeditiously to a full system of real time data-sharing among all entities involved in Part D. Congress should require CMS to report on its strategies to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS.

CMS should require states to redetermine the eligibility of *anyone losing Medicaid* to determine if that individual qualifies for the low-income subsidy (LIS, also known as Extra Help) as a result of eligibility for other qualifying benefits. CMS should also require states to redetermine LIS eligibility for *anyone who lost his or her Extra Help due to losing their deemed status*. Further, CMS and SSA should explore which agencies should oversee such redeterminations.

CMS should create a real time data-sharing system among all entities involved in Part D, and develop mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.

CMS should expand its point of service (POS) system to make its coverage available at the pharmacy for all dually eligible persons who experience plan enrollment and related drug dispensing problems at the pharmacy. Further, CMS should require pharmacies to use the POS system, and hold pharmacies harmless for good faith billings to the POS that turn out to be incorrect.

2. Beneficiaries Are Confused By The Part D Benefit Structure, And In Particular By The Gap In Part D Coverage Known As The “Donut Hole”

The standard Part D prescription drug benefit includes a deductible and beneficiary cost-sharing up to an initial coverage limit. Once that limit is reached, beneficiaries enter a “coverage gap,” known as the “Donut Hole,” and are responsible for the full cost of their drugs unless and until they reach a catastrophic threshold. Cost-sharing is reduced for all beneficiaries who get out of the Donut Hole, including those who are eligible for the low-income subsidy (LIS), also known as “Extra Help.” Unfortunately, many beneficiaries do not understand the benefit structure and the implications of the Donut Hole. Thus, they were not adequately prepared when they had to pay the full cost for their prescriptions. For example:

In September 2006, Mrs. L, the wife of a Medicare beneficiary, was charged \$73.59 for one of her husband’s prescriptions instead of the \$28.00 that she had been paying since the beginning of the year. The pharmacy technician had “no idea” why the cost of the drug increased. The wife called the drug plan and was told about the Donut Hole. The woman said that when she signed her husband up for Part D, she did not understand how the Donut Hole might affect her family. Because her husband would not exit the Donut Hole by December 31, he paid the Part D premium as well as the full cost of his drugs for the rest of 2006. Since learning of the Donut Hole and its impact, the woman has been blaming herself. She remarked that she knows she needs to educate herself (her husband is not mentally capable of doing so). She said that she has to work, to take care of her husband, to pay the bills, and to figure out how best to manage all health care options, and she does not have enough time in the day to sort out health insurance issues. She wonders how a program could be designed with such flaws.

Information provided to beneficiaries by both CMS and by drug plans often does not clearly explain the Donut Hole coverage gap. Even beneficiaries who understood that they would experience a gap in coverage did not understand how the initial coverage limit is calculated (full cost of all formulary drugs) and how their out-of-pocket costs to reach the catastrophic limit are calculated (beneficiary cost-sharing for formulary drugs up to the coverage limit, plus full cost of formulary drugs purchased at network pharmacies while in the gap.) Further, because Part D allows the costs of prescriptions to vary throughout the year, beneficiaries who relied on the plan’s price for their drugs when they chose a Part D plan may have underestimated what they would spend for prescriptions when they entered the coverage gap.

A. Paying For Drugs In The Donut Hole Creates Problems For Many Beneficiaries

Some beneficiaries who enter the Donut Hole have difficulty figuring out how to pay for their prescriptions. For example:

A case worker complained to the Center for Medicare Advocacy that many of her clients cannot afford their medications once they enter the Donut Hole. Some individuals have been assisted through the local Adult Protective Services program and other social services agencies that will pay for at least one month of medications. A few patient assistance programs have provided free medications for individuals who have a statement from their plan that they have reached the gap in coverage. Unfortunately, the case worker had clients who were going without medications or were spending their savings to buy medications.

The Donut Hole problems are exacerbated by the fact that some previous methods of paying for prescription drugs may no longer be available to Medicare beneficiaries. Some pharmaceutical assistance programs (PAPs), sponsored by drug manufacturers, no longer provide assistance to people enrolled in Part D. Even if a PAP will assist a Part D enrollee, neither the PAP's contribution toward the drug nor the beneficiary's cost-sharing counts towards the out-of-pocket amount the beneficiary needs to spend in order to get out of the Donut Hole. Similarly, assistance provided by AIDS Drug Assistance Programs (ADAPs) does not count to get out of the Donut Hole.

CMS encourages beneficiaries to consider using generic drugs and to enroll in plans with enhanced drug coverage that includes coverage through the Donut Hole. However, changing to a generic drug is not always possible. Many people with cardiac problems, cancer, multiple sclerosis, and other ongoing conditions rely on new, brand-name drugs for which there are still no generic equivalents. Most plans that offer Donut Hole coverage only pay for generic drugs in the gap. A few plans provide gap coverage for brand-name drugs, but there are only a few such plans, they are costly, and they are not available in every state. Even fewer such plans are available in 2007 than in 2006.¹ Thus, these plans provide no assistance to beneficiaries for whom a generic drug is either not available or not medically indicated.

B. Lack Of Knowledge About How The Donut Hole Works Often Leaves Beneficiaries Unprepared For This Gap In Coverage

Beneficiaries often do not know when they are approaching the Donut Hole or if and when they will reach the catastrophic coverage amount. Part D plans are supposed to include information in the monthly summary of benefits they send to plan enrollees so that enrollees can calculate when they will reach the Donut Hole. As shown by Mrs. L's story, however, that information may not be provided at all or may not be provided in a manner understood by beneficiaries. Problems also occur when beneficiaries try to predict whether their drug costs are high enough to get them through the coverage gap. For example:

A Florida-based advocate worked all year with the CMS regional office on behalf of a dual-eligible beneficiary who experienced continuous enrollment and disenrollment problems. Because the beneficiary's drug costs are so high, the advocate believed that the beneficiary should have gotten through the Donut Hole and therefore not been charged any co-payments for her drugs. However, neither the plan nor CMS could tell the advocate when the beneficiary had reached the

¹ In 2006, 2.3% of PDPs offered coverage for generic and brand-name drugs during the coverage gap (Donut Hole). That number falls to 1.4% in 2007. J. Hoadley, E. Hargrave, K. Merrill, J. Cubanski, T. Neumann, "Benefit Design and Formularies of Medicare Drug Plans: A comparison of 2006 and 2007 Offerings – A First Look" (Kaiser Family Foundation, November 2006), at p. 16.

catastrophic threshold. The e-mail response from CMS seemed to indicate that the beneficiary would still be charged co-payments after she reached the catastrophic threshold, even though federal law states otherwise.

Beneficiaries cannot calculate their expenses if they do not know when they will have to start paying for their drug costs in full or when they have reached the catastrophic limit. Beneficiaries' plans and CMS must ensure that Part D enrollees have the information they need and that beneficiaries with very high drug costs get the full Part D benefit to which they are entitled.

Recommendations

Congress should eliminate the Donut Hole. If the Donut Hole is not eliminated, Congress should, at a minimum, authorize payments by AIDS Drug Assistance Programs (ADAPs) and pharmaceutical assistance programs (PAPs) to count towards the beneficiary out-of-pocket spending limit.

CMS and Part D plans should be required to provide beneficiaries with clear and accurate information about Part D, individual plan offerings, and in particular, about the Donut Hole coverage gap. This information should include the following:

- Materials from CMS and the enrollee's plan that explain how the initial coverage limitation and beneficiary out-of-pocket expenses, including Donut Hole payments, are calculated should be mailed to beneficiaries;
- Monthly statements that clearly indicate the total amount of payments that have been made that count towards the individual's initial coverage limit and beneficiary out-of-pocket responsibilities should be mailed to beneficiaries; and
- Monthly statements that indicate, after the initial coverage limit has been reached, all costs that continue to count towards the out-of-pocket limit in the Donut Hole and how much more is needed to reach catastrophic coverage should be mailed to beneficiaries .

3. Beneficiaries Cannot Be Guaranteed That Premiums Will Be Withheld From Their Social Security Checks As Requested, Or That The Premiums They Pay Will Reach The Part D Plan In Which They Are Enrolled

Paying premiums for the Part D plans they have chosen is a challenge for many beneficiaries. Many beneficiaries chose to have Part D premiums withheld from their Social Security checks and paid directly to their plans, as they are accustomed to doing with Part B premiums. For some, Social Security withholding was never implemented. For others, Social Security withholding was implemented incorrectly. Some beneficiaries received refunds of their withheld premiums that were not due them, while others who were due premium refunds waited months to receive the money that was owed them. For example:

Mrs. X received an incorrect premium refund in August and repaid the money by sending a personal check to her drug plan, rather than to CMS. She then received a bill from her drug plan for a total of three months' premiums, September, October, and November. These premiums had already been deducted from her Social Security benefit, two payments from her October benefit and one from her November benefit. An advocate contacted the drug plan on her behalf, with a representative of the Social Security Administration on the phone, to verify that the premiums had been deducted. The information was to be sent to the drug plan's finance department, but confusion about the three months' payment has not yet been resolved.

At the same time, the advocate learned that Mrs. X's account with her drug plan had been changed from Social Security withholding to direct pay. The advocate asked if this change was made because the beneficiary paid the "refund" with a personal check. The customer service representative could not answer; she did not have access to payment information. The client had not requested to have her payment method changed to direct pay. The drug plan representative could not talk about payment history.

Another example:

An advocate was concerned about finding a safe and effective course of action for Mrs. R, whose Part D premiums throughout 2006 had never been withheld from her Social Security check as she requested. Mrs. R. is understandably concerned about when and how the year's worth of premiums will be deducted from her Social Security check. In particular, she is worried that, with the press of obligations, she will not have the funds to make a lump-sum payment if requested; the payment issues have left her with a lack of confidence whether to use the Part D benefit at all.

These stories illustrate the complex and apparently intractable nature of premium-withholding problems. Whether Mrs. X's issue was resolved was impossible to confirm despite a three-way conversation with SSA, the plan, and the client and her advocate. Mrs. R's problem continued throughout 2006 and had not been resolved by the end of the year.

The Center for Medicare Advocacy hears regularly from advocates who generally advise clients to ask for direct billing from the plan, rather than premium-withholding, because the withholding system is so broken. While this recommendation is an effective short-term solution, it denies beneficiaries their right under the law to use the premium-withholding system so familiar to them from Medicare Part B, a system that, under Part D, has fallen victim to the complexities and inefficiencies of a program dependent on hundreds of private plans.

CMS has admitted that problems exist with its system of withholding the amount of the Part D premium from beneficiaries' Social Security checks and transmitting that amount to beneficiaries' Part D plans. In a hearing before the Senate Finance Committee in early September 2006, CMS acknowledged that the problem of premium-withholding had initially affected more than half a million beneficiaries. It claimed, at that time, that it had resolved most of the problems and that only about 150,000 remained to be addressed. Later in the fall of 2006,

however, with problems continuing, CMS changed the default setting for payment of premiums on its web-based Plan Finder, from premium-withholding to direct billing from the Social Security check. A beneficiary wishing to have premiums withheld from his or her Social Security check cannot choose that option on-line but “will be contacted” by CMS to make specific arrangements. The number of beneficiaries still experiencing problems with premium-withholding is unknown, but problems still persist for many:

- Premium withholding continues to occur without beneficiary authorization or continues after the beneficiary has disenrolled from the plan or is not stopped when a beneficiary so requests.
- Premiums are not withheld when a beneficiary has so requested. Some beneficiaries have had no withholding throughout 2006 and are understandably anxious that all the premiums will be taken from a single Social Security check, leaving them with little or no income for the month.
- Withheld premiums have been refunded to many beneficiaries, in some cases correctly and in others, incorrectly. When CMS sought to recover the incorrectly-refunded premiums, it failed to notify beneficiaries of their right to be excused from recovery.
- Plans have still not received payment from CMS or SSA of premiums apparently withheld.

Recommendations

Congress should hold oversight hearings to understand the issues that make premium withholding so unreliable and should require CMS to solve these problems.

CMS should notify all beneficiaries who received incorrect premium refunds in 2006, and all beneficiaries for whom premium withholding has been delayed, of their right to seek a waiver of the recovery of these funds.

CMS should ensure that all plans have been paid all premiums owed for beneficiaries who asked for premium withholding in 2006 (so that the burden is not left with individual beneficiaries to work out problems on their own with their plans).

4. The Process For Getting Coverage Of Drugs That Are Not On A Drug Plan’s Formulary Is Confusing, Complicated, And Often Not Understood By Beneficiaries

In promoting Part D, CMS assured beneficiaries that they would have access to all of their medically necessary prescription drugs. What CMS failed to explain to beneficiaries is that they might have to file for a “coverage determination” and pursue an appeal if the drug they need is not on their plan’s formulary or is subject to certain restrictions, such as a limitation on the number of dispensable pills (“quantity limits”) or the need to request the plan’s permission before the drug is prescribed and paid for (“prior authorization”). The process for requesting a coverage determination and then an appeal is complicated, and most beneficiaries do not even understand this process, or the fact that they have the right to seek coverage for a drug not on their plan’s formulary.

A. Beneficiaries Are Not Adequately Informed Of Their Right To Request A Coverage Determination And File An Appeal

The Part D appeals process cannot begin unless and until a beneficiary who is denied coverage for a drug at the pharmacy affirmatively requests a formal “coverage determination” from his or her Part D drug plan. A coverage determination can only be issued by the drug plan itself; the denial at the pharmacy counter has no legal effect. The formal coverage determination from the plan should explain why the plan will not pay for the drug and how to start the appeals process.

Most beneficiaries who are denied coverage for their prescribed medications need to request a special type of coverage determination known as an “Exception.” An Exception may include a request to cover a drug that is not on the formulary, a request to reduce the cost-sharing for a drug, a request to provide a larger dose of a drug than the formulary limit, or a request to receive the prescribed drug without first trying a less expensive drug (“step therapy”). An Exception may also include a request to provide a drug without first getting prior authorization from the drug plan.

Unfortunately, beneficiaries are not adequately informed of the need to request a coverage determination. As a consequence, they never contact their drug plan for a coverage determination and they never enter the appeals process. For example:

After waiting two weeks for her refill, Mrs. F, a Maryland Medicare beneficiary, called the mail-order pharmacy used by her plan, only to be told that her prescription could not be refilled without prior authorization from the drug plan. If she had not called the pharmacy, she would not have known that she needed to request prior authorization from the drug plan before it would cover her drug. Even after she called, the mail-order pharmacy never sent her the notice explaining her rights. Thus, she did not know that she had a right to request an Exception to the prior authorization requirement.

Advocates continue to report that pharmacies are not providing beneficiaries with the CMS-approved notice, “*Medicare Prescription Drugs and Your Rights*,” which explains in general the right to contact one’s plan to request an Exception or other coverage determination. In December, an advocate who saw that the notice was not posted at a large chain drug store in suburban Washington, DC, was told that the pharmacy tells beneficiaries to call their plan, without giving them anything in writing or posting the notice.

Medicare regulations require Part D plans to arrange with their network pharmacies either to post the generic “*Medicare Prescription Drugs and Your Rights*” or to hand the notice to a beneficiary whose prescription has been denied. Posting of the notice provides very little protection. The notice is often posted in a place that makes it difficult to read. Moreover, because the notice is generic, telling beneficiaries only of their right to request an exception and the need to contact the plan, beneficiaries do not know what information they will need to provide in order to get their prescription covered or exactly how to contact their plan.

Furthermore, neither CMS nor the plans take responsibility when advocates complain that beneficiaries are not being informed of their rights to ask for an Exception and then to appeal. CMS says the plans are required to ensure distribution of the generic notice; plans claim they have done their job in educating pharmacies.

B. Beneficiaries Lack Plan Information For Evaluating A Prior Authorization Request

Even if, as in the case of Mrs. F, the pharmacy tells a beneficiary that prior authorization from the plan is required before a drug will be covered, the beneficiary still does not have all the information he or she needs in order to take action to get his or her medication. Drug plans do not make available on their web site or through their customer service centers the criteria they use to evaluate a prior authorization request. Thus, beneficiaries, their doctors, and their advocates do not have the information they need to support a request for prior authorization or a request for an Exception to a prior authorization requirement.

C. The Part D Appeals Process Includes Conflicting Directives Concerning The Effect Of The Attending Physician's Opinion On An Exception Request And Appeal

A beneficiary must have the support of the prescribing physician in order to succeed with an exceptions request. Indeed, the Medicare statute makes the opinion of the attending physician concerning his or her patient's need for a non-preferred drug the controlling factor in determining coverage. However, the Part D regulation specifically downgrades the effect of the physician's opinion to such an extent that it is not clear whether any deference is given. Thus while beneficiaries must obtain a supporting document from their physician even to enter the appeals process, Part D plans are not required to respect the physician's opinion.

This is particularly problematic when the beneficiary and physician seek an Exception for approval of an "off-label" use of a drug approved by the Food and Drug Administration (FDA). The use of drugs "off-label" is legal in the United States and is governed by strict rules for marketing. In many situations, physicians and their patients have determined over time that certain drugs approved by the FDA for one purpose also help with a different medical problem. Yet Part D plans do not defer to the opinion of the treating physician, even when the off-label use is supported by scientific literature, proven safe and effective over a substantial amount of time, and covered by the beneficiary's state Medicaid program. For example:

In 1995 Mrs. B, a dually eligible beneficiary in Florida, was prescribed an off-label drug to treat her multiple sclerosis (MS). As a result of the drug, she remained symptom-free, and she experienced no side effects. As required, Mrs. B looked to Part D to cover this drug in 2006. She chose a Part D plan because the plan representative said the drug was on the formulary. However, in April 2006, the drug plan said it would no longer cover the drug. The woman requested an Exception, and the plan asked her physician and her attorney to provide two national and professional medical journals to show why the use of the drug was medically reasonable to treat MS. Despite the fact that the beneficiary's medical record established that the drug had been effective for 11 years, and despite the fact that four peer-reviewed medical journal articles were submitted, the plan denied coverage of the drug. An Administrative Law Judge ruled in December that the drug was safe and effective and medically necessary for the woman, and ordered the drug plan to cover the drug. However, because the woman stopped taking the drug at the end of March, her symptoms returned.

D. Part D Complaint Mechanisms Are Not Prompt Or Reliable, Making The Process More Difficult For Beneficiaries

CMS has established a number of mechanisms through which beneficiaries may seek redress of problems with their drug plan. Beneficiaries may seek a coverage determination and appeal if a drug is not covered, file a grievance with the drug plan if they have a complaint that does not involve drug coverage, and/or file a complaint by calling the Medicare hotline, 1(800)MEDICARE. As illustrated below, these mechanisms are ineffective.

Mr. S, a New York beneficiary, and his doctor requested an expedited (72 hour) appeal after his drug plan said it would no longer cover one of his drugs. When no response was received, the beneficiary called the plan three times. He waited each time for about 45 minutes, trying to speak to a plan call center supervisor, and was disconnected each time before speaking to a supervisor. Finally, the beneficiary was called by the plan and told that the drug in question was not covered. The telephone representative did not provide any further explanation or describe additional appeal rights. The beneficiary did not receive written notice of the denial. The beneficiary subsequently called 1(800)MEDICARE to complain about the process. CMS's customer service representative told the beneficiary that the Medicare Call Center has no control over appeals issues and that he should contact the drug plan.

Recommendations

Congress should redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.

Congress should require Part D plans to give deference to the opinion of the beneficiary's attending physician when making coverage decisions and should require CMS to delete the provision to the contrary in its regulations [42 CFR §423.578(f)].

Congress should authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act.

CMS should require plans to provide a written coverage determination electronically at the pharmacy whenever a drug is not covered. The written coverage determination must explain why the plan will not pay for a drug and describe beneficiary appeal rights and explain how to request the next level of review.

CMS should require Part D plans to include on their web site, through their customer service centers, and in their written materials, information about whether each drug on their formulary requires prior authorization or other utilization management tools, and the criteria used by the plan in determining whether the precondition to Part D coverage has been met.

CMS should ensure that Part D plans comply with required appeals and grievance processes, that plan call centers respond appropriately to beneficiaries, and that Medicare “customer service” representatives provide accurate information and keep track of beneficiary complaints.

CMS should exercise its enforcement authority to take actions against Part D plans that do not provide adequate notice, fail to meet the regulatory time frames for deciding a coverage determination or an appeal, or fail to train their call center staff adequately.

CONCLUSION AND RECOMMENDATIONS

The stories presented here illustrate a variety of problems that continue to affect Part D beneficiaries at the end of the first year of program implementation. While each of these problems could be remedied by certain changes in program operations, they all derive, in large part, from the lack of uniformity in Medicare Part D and its reliance on hundreds of private plans. Although some people are better off than they were prior to Medicare Part D, too many remain confused and frustrated with the complexities and limitations of the drug program. All beneficiaries would be better off with a redesigned benefit that is standardized, available throughout the country, and administered through the traditional Medicare program.

BASED ON OUR EXPERIENCE WITH MEDICARE BENEFICIARIES AND THEIR HELPERS, THE CENTER FOR MEDICARE ADVOCACY RECOMMENDS THE FOLLOWING.

THESE RECOMMENDATIONS WILL IMPROVE MEDICARE’S PRESCRIPTION DRUG BENEFIT, MAKING IT MORE VALUABLE FOR BENEFICIARIES AND MORE COST-EFFECTIVE FOR TAXPAYERS.

Recommendations for Congress:

1. Congress should redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.
2. Congress should eliminate the Donut Hole. If the Donut Hole is not eliminated, Congress should, at a minimum, authorize payments by AIDS Drug Assistance Programs (ADAPs) and pharmaceutical assistance programs (PAPs) to count towards the beneficiary out-of-pocket spending limit.
3. Congress should require Part D plans to give deference to the opinion of the beneficiary’s attending physician when they make coverage decisions.
4. Congress should authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary’s state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act.
5. Congress should hold oversight hearings on the implementation of Part D. The hearings should include an inquiry into the special problems of dually eligible beneficiaries, the withholding of premiums by plans and Social Security, and CMS’s role in setting and enforcing standards for plan participation.

6. Congress should require CMS to expeditiously establish a full system of real time data-sharing among all entities involved in Part D. Congress should require CMS to report its plans to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS.

Recommendations for the Centers for Medicare & Medicaid Services (CMS)

1. CMS should require states to redetermine the eligibility of *anyone losing Medicaid* to determine if that individual qualifies for the low-income subsidy (LIS, also known as Extra Help) as a result of eligibility for other qualifying benefits. CMS should also require states to redetermine LIS eligibility for *anyone who lost his or her Extra Help due to losing their deemed status*. Further, CMS and SSA should explore which agencies should oversee such redeterminations.

2. CMS should create a real time data-sharing system among all entities involved in Part D, and develop mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.

3. CMS should expand its point of service (POS) system to make its coverage available at the pharmacy for all dually eligible persons who experience plan enrollment and related drug dispensing problems at the pharmacy. Further, CMS should require pharmacies to use the POS system, and hold pharmacies harmless for good faith billings to the POS that turn out to be incorrect.

4. CMS and Part D plans should be required to provide beneficiaries with clear and accurate information about Part D, individual plan offerings, and in particular, about the Donut Hole coverage gap. This information should include the following:

- Materials from CMS and the enrollee's plan that explain how the initial coverage limitation and beneficiary out-of-pocket expenses, including Donut Hole payments, are calculated should be mailed to beneficiaries;
- Monthly statements that clearly indicate the total amount of payments that have been made that count towards the individual's initial coverage limit and beneficiary out-of-pocket responsibilities should be mailed to beneficiaries; and
- Monthly statements that indicate, after the initial coverage limit has been reached, all costs that continue to count towards the out-of-pocket limit in the Donut Hole and how much more is needed to reach catastrophic coverage should be mailed to beneficiaries .

5. CMS should notify all beneficiaries who received incorrect premium refunds in 2006, and all beneficiaries for whom premium withholding has been delayed, of their right to seek a waiver of the recovery of these funds.

6. CMS should ensure that all plans have been paid all premiums owed for beneficiaries who asked for premium withholding in 2006 (so that the burden is not left with individual beneficiaries to work out problems on their own with their plans).
7. CMS should require plans to provide a written coverage determination electronically at the pharmacy whenever a drug is not covered. The written coverage determination must explain why the plan will not pay for a drug, describe beneficiary appeal rights, and explain how to request the next level of review.
8. CMS should require Part D plans to include on their web site, through their customer service centers, and in their written materials, information about whether each drug on their formulary requires prior authorization or other utilization management tools, and the criteria used by the plan in determining whether the precondition to Part D coverage has been met.
9. CMS should ensure that Part D plans comply with required appeals and grievance processes, that plan call centers respond appropriately to beneficiaries, and that Medicare “customer service” representatives provide accurate information and keep track of beneficiary complaints.
10. CMS should exercise its enforcement authority to take actions against Part D plans that do not provide adequate notice, fail to meet the regulatory time frames for deciding a coverage determination or an appeal, or fail to train their call center staff adequately.

THE CENTER FOR MEDICARE ADVOCACY

Founded in 1986, the Center for Medicare Advocacy is a national, non-profit, non-partisan organization that works to ensure fair access to Medicare and quality health care. The organization is headquartered in Connecticut, with offices in Washington, DC and throughout the country.

The Center responds to over 7,000 calls and emails annually from older people, people with disabilities, their families, and support networks. The Center provides in-person and web-based training throughout the United States. The organization is a partner in Connecticut's SHIP (State Health Insurance and Assistance Program, known in Connecticut as CHOICES), providing training, educational materials, and direct assistance with Medicare, Part D, and related programs. Since November 15, 2005, when beneficiaries could first enroll in Part D, through May 15, 2006, when enrollment closed, the Connecticut CHOICES program handled over 38,000 calls, more than two-thirds of which were about Part D. As the CHOICES legal support center, the Center for Medicare Advocacy handled, or provided guidance about, a significant portion of these calls.

As a result of a grant from a national foundation, the Center for Medicare Advocacy also provides advocacy, training, telephone and on-line assistance regarding Part D on behalf of beneficiaries and their advocates throughout the country. The Center hosts two web sites: www.medicareadvocacy.org and www.fairmedicare.org.