Medicare Part D: Where Do We Stand? Where Are We Going?

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May 15, 2006, the end of the initial enrollment period for the new Medicare prescription drug program, has come and gone, but much still remains unaddressed and unclear regarding Medicare Part D. Such a seemingly simple thing as the May 15th deadline itself, which some 47% of seniors were unaware of, isn't actually the deadline for everyone. The Centers for Medicare and Medicaid Services (CMS) is allowing 3 groups to enroll after the end of the initial the May 15th deadline. These groups are the dually eligible (those having both Medicare and Medicaid), those approved to receive the low-income subsidy, and certain victims of Hurricane Katrina (Table 1). Given that these groups represent especially frail and vulnerable seniors, a similar group—those entering a long-term care facility—is being considered for eligibility to enroll outside the set enrollment periods without being subjected to a financial penalty.

Table 1.
Medicare Part D Enrollment Period

Enrollment Type	Affected Group	Time Period
Regular enrollment	All nonspecial Medicare beneficiaries that are eligible for Medicare D can use this process	*IEP*: November 15, 2006 • May 15, 2006 *AEP*: November 15, 2006 • December 31, 2006
Special enrollment	Accepted as dually eligible, or in the LIS and Hurricane Katrina evacuees	Ability to enroll outside AEP
	Dually eligible, those living in LTC facilities (SNF, ICF, MR), and Hurricane Katrina evacuees	Ongoing ability to change plan
	Facilitated enrollees: SPAP, LIS Medicare beneficiaries	Can make one change of plan

AEP=annual election period; ICF=intermediate care facility; IEP=initial enrollment period; LIS=low-income subsidy; LTC=long-term care; SNF=skilled nursing facility; MR=mental retardation; SPAP=state pharmaceutical assistance program

In addition, the exact number of those who have enrolled in the various prescription drug plans (PDPs) is still unclear. Legislative and regulatory changes that are likely coming will have a significant effect on how Medicare Part D evolves. And for prescribers, perhaps the biggest question is, "How will all of this affect our ability to dictate what medication gets dispensed?" One thing that is clear, however, is that with each passing day, many issues are being resolved and becoming clearer, while new issues are arising and causing more uncertainty.

Numbers Don't Add Up

There is still a great deal of confusion with regard to the numbers of enrollees in the Medicare Part D program. As of January 1, 2006, all 43 million elderly and disabled people on Medicare were given access to the Medicare Part D prescription drug benefit. The Bush Administration has claimed that as of June 11, 2006, nearly 38 million people were receiving benefits under Medicare Part D and that 5 million people with Medicare still lack prescription drug coverage (Table 2).

However, at the end of the day, the real numbers to look at are those showing how many Medicare beneficiaries moved from no or limited coverage prior to Medicare Part D to now having prescription drug coverage. In fact, the overwhelming majority of people already had coverage, either through state Medicaid programs, employer-sponsored plans, or managed care organizations before the introduction of Medicare Part D. Yet according to Medicare's own figures, just slightly more than half (9 million) of these 17.7 million Medicare ben-

eficiaries, including more than 3 million beneficiaries eligible for the low-income subsidy program still lack coverage today (Table 3).

The numbers that did add up as expected followed the "Pareto Principle." This principle states that "a limited group will control the vast majority of a resource." In the case of Medicare Part D, the limited group is comprised of UnitedHealth Group and Humana, and the resource is their members. Together, these plans provide coverage for 45% of those enrolled in PDPs and 33% of those enrolled in Medicare managed care organizations. UnitedHealth Group was able to accomplish this through its relationship with AARP, Walgreens, and organizations with a strong loyalty, as well as through name recognition among seniors. Humana was able to achieve its enrollment numbers based on price and strong marketing efforts by State Farm and Walmart.

Table 2.
Total Medicare Beneficiary Drug Coverage (June 11, 2006)

Drug Coverage (Medicare or Former Employer)	
• Stand-alone Prescription Drug Plan (PDP)	10.37
• Medicare Advantage (MA-PD)	6.04
• Medicare/Medicaid [autoenrollment]	6.07
• Medicare Retiree Drug Subsidy (RDS)	6.90
• FEHB Retiree coverage	1.60
• TRICARE Retiree coverage	1.86
• Veteran's Administration (VA) coverage	2.01
• Indian Health Service coverage	0.11
• Active workers with Medicare secondary payor	2.57
• Other retiree coverage, not enrolled in RDS	0.10
• State pharmeceutical assistance programs	0.59
Total	**38.22**
UNINSURED TOTAL	**5.00**

Table 3.
Total Medicare Beneficiary Drug Coverage (June 11, 2006)

	Millions
Total Beneficiaries Eligible for Low-income Subsidy (LIS)	**13.20**
Less: Drug coverage from Medicare or former employer	9.26
• SSA LIS approved	1.80
• Other deemed full/partial duals and SSI recipients	7.50
Less: Additional sources of creditable drug coverage	0.59
• Veteran's Administration (VA) coverage	0.35
• Indian Health Service coverage	0.11
• SPAP creditable coverage	0.13
Total: Remaining LIS-eligible beneficiaries	**3.25**

SPAP=state pharmaceutical assistance program; SSA=Social Security Administration; SSI=Supplemental Security Income

Changes for Next Year

Changes for 2007 have been promoted by many disenfranchised stakeholders. In the summer of 2003, politicians responded positively to proposed improvements in access to medications for millions of American seniors, which in turn translated into votes in the fall. However, seniors remain confused over the benefit, as well as the vast number of prescription plans available, and providers have become frustrated over the individualization of plans' coverage, which takes up a great deal of their valuable time. These areas of concern are forcing changes both from legislators, as well as CMS guidance.

During 2007, CMS plans to apply increasing pressure on PDPs to provide greater access to medications, as well as to improve their operational efficiency. Much of this is the direct result of provider and Medicare beneficiary frustration. A recent study showed that 94% of physicians remain confused about Medicare Part D, especially with regards to accessing specific medications. This has resulted in 70% of physicians spending 20% or more time on administrative tasks related to Medicare Part D. This was demonstrated following CMS' guidance to PDPs that after March 1, 2006, Part D plans may make only maintenance changes to their formularies, such as replacing brand name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness.

Legislative Changes

The legislative changes that will determine where Medicare Part D is headed now fall into several brackets, addressing enrollment issues, cost-sharing issues, access issues, and process issues. Concerning enrollment issues, several pieces of legislation are calling for opening the enrollment period to allow for some groups to enroll after May 15, 2006. While this is unlikely, there is a strong possibility

that the late enrollment penalty of 1% for each month without coverage will be voided during the first year of the program. Another enrollment issue that needs to be considered is related to the ability of a beneficiary to change plans. Many seniors have argued that they enrolled in PDPs based on incorrect information either from the prescription drug plan, their employer, or even the CMS Web site. Legislation would permit a one-time change of plan enrollment during 2006, as well as allow retirees back into their employer-sponsored plans.

In terms of cost-sharing issues, legislation would eliminate the disincentive for nursing home-eligible seniors who live outside of skilled nursing facilities. This is because dually eligible beneficiaries residing in skilled nursing facilities currently are exempt from copayments, whereas those living outside such facilities are responsible for making copayments. This has resulted in a significant disincentive for nursing home-eligible individuals utilizing home- and community-based waivers to live outside skilled nursing facilities.

Seniors remain confused over the Medicare benefit, as well as the vast number of prescription plans available.

With regard to medication access issues, some changes have occurred without legislative action. CMS announced that Part D PDPs may make only maintenance

Related Discussion:

On May 22, 2006, CMS Administrator Mark B. McClellan, MD, PhD, addressed the National Community Pharmacists Association's (NCPA) 38th Legislation and Government Conference, reflecting on where we've been...and where we are going with Medicare Part D and the Deficit Reduction Act (DRA). A summary of and excerpts from those remarks follow.

"As we shift our focus from enrollment and initial implementation of the Medicare drug benefit to integrating the new prescription benefit with our broader initiatives on promoting prevention and high quality care, we will need to continue to work together (with pharmacists) just as closely."

"During the past 2 years, pharmacists have been on staff, for the first time ever, in the CMS central office and every regional office. I want to be clear that this was not a one-time effort to gear up for the drug benefit—it's a permanent change in the level of pharmacist involvement in the management of our programs. Pharmacy perspectives are now an essential and integral part of our agency, just as prescription drugs are an absolutely essential part of modern medicine and now, for the first time, an integral part of Medicare."

"While we are still tabulating final enrollment numbers, we can report that more than 38 million people with Medicare now have good, secure coverage for prescription drugs. Enrollment in Part D-related coverage accounts for over 32 million of these beneficiaries."

"Because of our partnership with you, CMS was able to move quickly to address Part D implementation issues on many fronts. Many of the initial start-up difficulties were the result of millions of late-month enrollments and plan switches. We've addressed this in part by getting the message out about allowing a reasonable amount of time between when someone enrolls in a plan and when that person can use coverage."

"We've also taken further steps with the drug plans and states to ensure accurate and complete coverage data are available to pharmacists when beneficiaries first show up in the pharmacy. For example, plans are now using twice-a-month updates on coverage and co-pay status for their enrollees in the low-income subsidy."

"We are tracking the accuracy of plan data—which has now achieved very high levels."

"We've established 'business processes' with plans so they can quickly and automatically confirm the current eligibility and co-pay status of beneficiaries in our systems, and amend information if they are having difficulty with prescriptions."

"Consequently, we have seen major declines in the rate of casework requests we are getting, particularly related to dual and low-income subsidy eligibility and enrollment."

"Since January, wait times on our 1-800-MEDICARE customer service line have consistently averaged under 2 to 4 minutes. Even with the extraordinary interest on May 15—when we shattered our previous record of around 400,000 calls by handling over 640,000 calls in one day—we achieved an average wait time of less than 13 minutes. By the way, that previous record was set on January 2."

"We've seen major improvements in the prescription drug plans, with the vast majority of plans now answering most customer and pharmacist calls in less than 5 minutes."

"We listened to pharmacists concerns about co-branding with drug store logos on cards. Accordingly, to build on the steps we have already taken to enable Medicare beneficiaries to find out about convenient community pharmacies in each drug plan—and to avoid any potential enrollee confusion about where they can purchase their medication—co-branding on pharmacy benefit cards will be prohibited for the upcoming plan year."

"We also intend to work closely with the pharmacy community to implement the pharmacy provisions in the Deficit Reduction Act (DRA). As you know, the DRA will affect the way the Medicaid program calculates its Federal Upper Limit, used to determine the maximum level of reimbursement for drugs with generic competitors. This provision of the DRA represents a clear opportunity for states to save money on generic product acquisition costs. But actual savings will be dependent upon state actions with the new Federal Upper Limit."

"If states do not maintain the right incentives for generic utilization, any savings will be lost to higher and more expensive brand-name utilization. For this reason, CMS guidance encourages states to align incentives for generic utilization and

changes to their formularies. Legislation could take this a few steps further in requiring plans to grandfather individuals on their medications for as long as they are in a plan. In addition, the earliest piece of legislation introduced called for the federal government to cover the benzodiazepine medications, one of the excluded Medicare Part D therapeutic classes of medications.

Finally, with regard to process issues, legislation would mandate certain minimum standards for PDPs to meet in areas such as answering their telephones and providing timely feedback to patients and prescribers.

PPDs have the responsibility to assure that no beneficiary will be subject to discontinuation or reduction in coverage of the drugs they are currently using.

Controlling the Prescription

One thing that is certain is that as a result of Medicare Part D and other environmental changes, such as ePrecribing and consumer-driven health care, the power will shift from the physician to other groups with regards to the control of medications being dispensed. Historically, prescribers have had the first and final word in what drug is dispensed to a patient. Their decisions were based on their practice of medicine and, to some degree, their personal preference dictating which medication was best. Physicians would write a prescription and were assured that it would be filled as written. As a

consider paying pharmacists more in dispensing fees to support state savings from greater use of generics."

"More financial support to pharmacists that improve quality and reduce costs of drug coverage and chronic disease management is actually one of the key elements of our guidance to states in our 'Road Map to Medicaid Reform,' released in March, and I encourage you to take a look at the details."

"Under another provision of the DRA, CMS is required to collect and publicly post Average Manufacturer Prices (AMPs) to better inform the states and the public about the true price of prescription drugs. The goal of this DRA provision is to capture the most accurate pricing data possible to assure that the Federal government and State Medicaid programs are paying appropriately for generic drugs."

"Pharmacists have made it clear to us that unless AMPs are defined and calculated accurately and include only prices that are available to the 'retail class of trade,' AMPs will not accurately reflect prices available to retail pharmacies. We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement."

"We also recognize that pharmacists are especially concerned about the DRA provision that calls for AMPs to be posted beginning on July 1, 2006, because the more specific definition of AMP would not be reflected in the current AMP data as reported by manufacturers."

"Consequently, I am announcing today that CMS will not publicly release the current AMP figures. We do expect to share pricing information with the states, as we do confidentially with other types of drug pricing data, but only for purposes of helping them set up their billing systems appropriately and not for the purposes of setting reimbursements."

"Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms."

"We will be releasing this revised definition for public comment as a proposed rule. And we will also be developing an initial round of AMP data based on the new definition for public comment."

"I want to conclude by taking a step back and talking about the big picture for the future of retail pharmacy."

"I know there are a lot of concerns about tighter reimbursement rates per prescription. I can relate to this, having experienced the same kind of tightening in third-party payments in my own medical practice."

"I know there is some interest in potentially seeing new kinds of payment regulation from the Federal government. But speaking as a physician, government regulation of payments is not something I'd recommend to any health professional."

"I've experienced first hand the blunt effort to reduce health care costs by cutting payments to providers, because no one made the effort to find a better approach to keep quality health care affordable. I've lived through the frustration of watching my workload increase while payment rates not only went down, but got locked in and didn't keep up to support new and promising directions in higher-quality care."

"Tighter payments per service, like tighter payments per prescription, have been part of a fundamental trend in health care systems around the world. Such tightening of payment rates has occurred universally—universally when government gets involved in setting payments. But it's not a long-term solution to the challenges we are facing today, and in particular, the challenges in community pharmacy."

"Instead, focusing on spending health care dollars better, rather than just on reducing payment rates to reduce health care costs, deserves strong support from Medicare, and we are going to make it happen. Pharmacists and pharmacies have already demonstrated the great value they provide in the implementation of the Medicare drug benefit. They have also shown they can add much more—helping people find lower cost drugs like generics and therapeutic alternatives, helping people with multiple illnesses understand how to use their medications, and improving compliance."

"All of these things can improve quality of care and reduce overall health care costs. This helps us get to a health care system that provides the right care for every person, every time."

To view Dr. McClellan's remarks in their entirety, visit the CMS Web site at: http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1866.

Table 4.
Excluded Medicare Part D Medications

Specific Excluded Classes
- Over-the-counter (OTC) medications
- Barbiturates
- Benzodiazepines
- Prescription vitamins (except Niasin® and Niaspan®, as well as certain analogs and prenatal vitamins)

Specific Excluded Uses
- Weight-related (except when used to treat certain disease states, such as obesity and anorexia)
- Fertility
- Cosmetic
- Symptomatic relief for cough or colds

Those Covered by Part A or Part B for Specific Instances

Table 5.
Protected Medication Classes Under Medicare Part D

- Antidepressants
- Antipsychotics
- Anticonvulsants
- Antiretrovirals
- Immunosuppressants
- Antineoplastics

direct result of Medicare Part D, this decision has shifted to other groups having a much greater say in what particular medication ultimately is dispensed to the patient.

Additionally, in the past, on the basis of value judgments, patients or the payor played a role in the decision of what medication was dispensed. When the patient or their payor was faced with a decision about coverage of a specific medication, the decision was between choosing a preferred brand name medication and its less expense alternative. If the patient or payor did not see the value in the higher cost of the branded medication over the less expense alternative, the medication was changed from the physician's original order.

With the implementation of Medicare Part D, PDPs have the responsibility to assure that no beneficiary will be subject to discontinuation or reduction in coverage of the drugs they are currently using, except for clear scientific and cost reasons, including the availability of a new generic version of the drug. This has resulted in prescription plans aggressively using utilization tools, such as prior authorization, step therapy, quantity limits, and tiering, to direct access to preferred agents. These forces may prove to be much more powerful than a physician's pen in obtaining specific medications. As a result of these incentives and utilization tools, PDPs will be the most powerful entity in the process that decides which medication is dispensed.

Although some of the utilization tools being used by PDPs will result in improved medication use, others may represent inappropriate barriers to medication access. Unfortunately, PDPs are siloed in being responsible only for direct medication costs. As a result, their goal is to reduce drug utilization—not to improve overall care—which will drive them to implement barriers to access even appropriate medications.

The federal government, including CMS, has the ability to dictate formulary recommendations. This has resulted in some products having a forced inclusion on a Medicare Part D formulary, while others have been excluded. Thus, under the Medicare Modernization Act, the federal government has developed a list of certain medications that are excluded from coverage under Medicare Part D (Table 4), while at the same time mandating that plans cover substantially all medications in 6 drug classes (Table 5). The ultimate result of federal government involvement, either through legislation or CMS regulations, is more or less access to certain drugs for Medicare beneficiaries. This shift from prescribers having unobstructed authority in deciding what drug is dispensed to their patients will continue to build, moving rapidly to the groups that control the dollars and rules.

So Where Is Medicare Part D Headed?

Unfortunately, the answer to this question is not one that will be answered based on a sound clinical basis or even a sensible health policy. Instead, it will be determined by Washington politics and is very much dependent on the results of the next few elections. Much debate has centered on removal of the noninterference clause, which prohibits the federal government from negotiating prices with pharmaceutical companies. Whatever direction Medicare Part D takes, clearly it will represent a change for all stakeholders involved in the care of seniors. ALC

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