
Medicare Prescription Drug Coverage— What It Means for Today and Tomorrow

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The introduction of the Medicare prescription drug program on January 1, 2006 truly marked a major change in not only how Medicare providers now write prescriptions, but also how medicine is practiced. This change was the result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, whose title was shortened to the Medicare Modernization Act (MMA). The modernization of a 40-year-old programs that involves 42 million beneficiaries and countless millions of providers is, of course, no easy task. It is made even more complex as a result of an ever-increasing number of seniors, innovative new technologies, and limited resources of providers with geriatric expertise. Of course, the major change that providers now face is the direct result of the new Medicare Part D. This change will have a major impact on practices not only today, but also perhaps even more profoundly on how medicine is practiced in the future.

What It Means Today

One of the most important starting points in Medicare Part D is the fact that seniors need to know that they have until May 15, 2006 to enroll in a prescription drug plan (PDP) or be subject to a late enrollment penalty. Specifically, for every month that an eligible beneficiary fails to enroll in a PDP or be covered by a creditable plan (eg, an employee retiree program or VA benefit), he or she will pay a premium of 1% for each uncovered month for the rest of the time that he or she receives drug coverage from Medicare Part D. Seniors who fail to enroll until 70 years of

age and are not covered by any credible coverage once Medicare Part D is in effect will pay a 60% higher premium for Plan D drug coverage.

By now, you are aware that the prescriptions that you are writing for your Medicare patients are likely being paid for differently as result of the new Medicare prescription drug coverage benefit. The significance of this change is reflected in Table 1, which shows the pre and post Medicare Part D coverage of Medicare beneficiaries' prescriptions. For example, PDPs that did not exist prior to January 1, 2006 are now responsible for

34% of the prescriptions written. These penalties have been crafted by Congress to prompt beneficiaries to enroll at the beginning of Medicare Part D, instead of waiting to join only when health problems develop and drug costs rise. The late enrollment fee is intended to decrease the number of cash-paying patients by half, which Centers for Medicare and Medicaid (CMS) hopes is a significant underestimate of those who will take advantage of this benefit. CMS's initial estimates were that 94% of Medicare beneficiaries who were eligible for Medicare Part D would enroll. Recent information suggests that seniors remain very confused about this benefit. So confused, in fact, that only 15% of those who received the low-income subsidy application completed and returned it. This despite the fact that this group would save 83% to 100% in out-of-pocket expenditures.

Thus, the most immediate issue is and will continue to be getting patients to enroll in Medicare Part D. For accessing medications through Medicare Part D will be in effect only after a Medicare patient has joined a Medicare prescription drug program.

Benefits of Medicare Part D

There are some benefits from Part D that may positively impact Medicare providers. These mainly involve the revenue side of the provider's practice. Many practices have utilized the Medicare Part D program as a marketing initiative to encourage community seniors and their caregivers to join their practice on the basis of their understanding and willingness to share information concerning Medicare Part D. This usually occurs during a health fair or other event that focuses on Medicare Part D education. Another opportunity for revenue enhancement exists through the provision of medication therapy management services (MTMS). These services can be administered by a physician and billed to a PDP. Perhaps the most significant revenue enhancement, however, will come from improving patient outcomes through increased access to medications.

The current Medicare payment system is based on the volume of acute care services without differentiation for quality. In fact, the ar-

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gument can be made that in today's environment, high-quality practices are penalized because they often incur higher expenses through utilizing electronic health records, treating a lower volume of patients, and focusing on preventive care. These practices, while delivering superior quality outcomes, are not compensated appropriately. Medicare has begun the move to a pay for performance system, in which practices that deliver superior outcomes will be compensated accordingly. Practices will have to assume an active role in ensuring that their patients have access to medications that provide improved outcomes, of which enrollment in a Medicare Part D will be a critical component.

Developing efficient and effective systems for accessing formulary medications can also decrease expenses. This is more of a preventive measure, because practices that are not proactive will ultimately suffer increased operational expenses through the need to field phone calls to gain access to non-formulary medications or change a medication to a formulary listing.

The exceptions process, which ensures that beneficiaries have access to the prescription drugs they need, is unique to the drug benefit. It provides a straightforward process for an enrollee to obtain a covered Part D drug at a more favorable cost-sharing level or obtain a Part D drug that is not on the plan's formulary. Enrollees and/or their physicians may request an exception under the following circumstances:

- The enrollee is using a drug previously covered on a plan's formulary, but that has been removed during the plan year for reasons other than safety;
- A nonformulary drug is prescribed for the enrollee that the physician believes is medically necessary;
- An enrollee is using a drug that has been moved from a preferred to a nonpreferred cost-sharing tier during the plan year; or
- The physician prescribed a drug for the enrollee that is included in a plan's more expensive cost-sharing tier because the physician believes the drug included in the less expensive cost-sharing tier is medically inappropriate for the enrollee.

Generally, plans must grant exceptions when they determine that it is medically appropriate to do so.

Table 1.
Changing Prescription Coverage*

Payor	Before Medicare Part D	After 2005
No drug coverage	38%	19%
Employer sponsored	28%	18%
Medicare managed care	15%	26%
Medigap	7%	2%
SPAP	2%	0%
PDP	0%	34%

*University of the Sciences in Philadelphia estimate of enrollment projections, December 2005.
PDP=prescription drug plans; SPAP=state pharmaceutical assistance programs.

If the exceptions request involves a plan's tiered cost-sharing issue, the Part D drug being prescribed may be covered if the prescribing physician determines that the PDP's preferred drug for treatment of the same condition would not be as effective as the prescribed drug or would have an adverse effect on the enrollee, or both. If the enrollee requests coverage of a non-formulary drug, the drug may be covered if the prescribing physician determines that all of the drugs on the formulary would not be as effective as the nonformulary drug or would have an adverse effect on the enrollee, or both. In both cases, the plan would have to agree with the physician's determination.

Once a plan makes an unfavorable coverage determination, such as denying an exception request, the enrollee or his or her appointed representative may appeal the plan's decision. The Part D appeals process is modeled after the currently successful Medicare Advantage Prescription Drug Plans' appeals process. Practices that develop an efficient and effective process for handling these appeals and exceptions will not incur the additional operational costs that come with this new burden.

Problems Surfacing

Problems are surfacing that should come as no surprise with a massive federal program with such a high level of complexity. Again, these problems fall into 2 primary areas: enrollment and medication access. Enrollment issues involve failure to enroll in any plan or failure to enroll in the right plan, and include the unique problem of the "triple

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eligibles." These are people who are covered not only by Medicare and Medicaid (dual eligibles), but also have employer-sponsored pharmaceutical coverage. Such individuals were autoenrolled in a plan by CMS, which removed them from their employer-sponsored plan. This is not an insignificant problem. In 2001, the Medicare Payment Advisory Commission (MedPAC) estimated that 61,000 Americans with Medicare and Medicaid had supplemental insurance from their employer.¹ Sixty percent of employers said that they will drop retiree drug coverage or both drug and medical coverage for members that enroll in a Part D plan.² The result is that "triple eligibles" are likely to find themselves and their spouses excluded from their employer-sponsored health care plan and enrolled in an inferior program without their consent. To correct this problem, the "triple eligibles" group must contact CMS and disenroll from their autoenrolled Part D plan.

Another problem is that because of a limited definition of

long-term care, nursing care-eligible seniors living outside a skilled nursing facility will likely miss out on several important opportunities available to especially frail seniors. These opportunities include access to a special enrollment period, special packaging through institutional pharmacy providers, no cost sharing for the dually eligible, and greater access to nonformulary medications. Unfortunately, long-term care settings include only skilled nursing facilities, intermediate care facilities, and mental retardation facilities, and do not include assisted living facilities. As a result, there is a financial and clinical disincentive to live outside the long-term care setting. States, such as New Jersey, recognize this and are covering all cost sharing for the dually eligible so that residents utilizing home- and community-based waivers to live outside of skilled nursing facilities are not penalized.

Besides the general difficulties inherent in dealing with restrictive formularies with prior authorization, tiering, and quantity limits, there are 3 unique issues with regards to medication access. These issues involve Medicare Part D-excluded medications, the use of off-label medications, and CMS's evaluation of therapeutic equivalents.

Medicare Part D medications that are not on formulary can be accessed through the exceptions and appeals process. However, not all medications are Medicare Part D medications, and there are specific medications that, by law, are excluded from coverage. The MMA excludes coverage of certain medications from Medicare Part D,

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based on their class and use. These medications include:

- Specific excluded classes
 - Over-the-counter (OTC) medications
 - Barbiturates
 - Benzodiazepines
 - Vitamins (except prenatal)
- Specific excluded uses
 - Weight-related (except when used to treat obesity)
 - Fertility
 - Cosmetic
 - Symptomatic relief of cold or cough

These medications cannot be covered by Medicare Part D funds, but PDPs can choose to provide them at no cost, using other sources of funding. Some PDPs have chosen to do this, especially for non-sedative antihistamines and OTC proton pump inhibitors because they believe this will be less expensive for them than paying a percentage of a prescription-equivalent medication. While all states will cover some or all benzodiazepines and barbiturates for dual-eligibles, Texas and Tennessee are the exceptions.³

PDPs can cover a drug only if it is medically accepted, as defined in the Medicaid statute. Indications that are supported in peer-reviewed medical literature, but not yet reflected in the compendia (eg, American Medical Association Drug Evaluations and American Hospital Formulary Service Drug Information), are “not medically accepted.” This will affect how patients who have conditions responding to off-label uses of drugs will gain ac-

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cess to effective medications.

With regard to evaluation of therapeutic equivalents—in an effort to encourage the use of generic medications—CMS has issued such guidance as categorizing Lexapro[®] (escitalopram) and Celexa[®] (citalopram) to be therapeutically equivalent, allowing plans to cover less expensive citalopram at the exclusion of escitalopram. This came about late in the formulary review process when CMS mandated that formularies must include “substantially all” the medications in 6 therapeutic drug classes, 1 of which is the antidepressant class. The reason for the use of the term “substantially all” and not simply “all” is that CMS added that plans did not need to include escitalopram on their formularies because another drug, citalopram, was an acceptable therapeutic alternative.⁴ This despite the fact that escitalopram is the most widely used antidepressant in the long-term care setting, currently being taken by hundreds of thousands of long-term care residents. Addi-

tionally, citalopram is not the generic equivalent of escitalopram. In fact, the 2 drugs are structurally different and have a different clinical effect. Likewise, the FDA considers there to be differences between the 2 drugs, with escitalopram being approved for treatment of anxiety, while citalopram is not indicated for that purpose. In clinical studies, citalopram was less effective and people taking it had more side effects. Although CMS has stated that they want formularies to follow clinical guidelines, established mental health treatment guidelines for depression, such as those developed by American Psychiatric Association, unequivocally state that drugs to treat depression are not interchangeable.

This is an example where CMS is best leaving issues of clinical concern to the FDA and other established organizations, rather than forcing the exclusion of widely used medications from plan formularies, which will cause disruption to care and be very problematic. As CMS becomes increasingly involved in formulary management, these types of actions that encourage generic over brand usage are likely to increase as a means to control costs. It is not entirely clear how patients, especially the frail elderly, will respond to regulations that force nonequivalent therapeutic interchanges. This will require careful physician involvement to ensure that adverse consequences of such actions are minimized.

What Will Happen Tomorrow?

Legislation that was recently introduced includes provisions to

Take-Away Message

- The Medicare Prescription Drug Coverage Plan D will significantly change how Medicare prescriptions are covered.
- Enrollment problems include the inappropriate autoenrollment of seniors already covered by an employer-sponsored plan, as well as the limited definition of long-term care.
- Access issues involve medications specifically excluded from coverage under Medicare Part D, as well as the off-label use of medications and CMS's evaluation of therapeutic equivalents.

ROI

- Practices can enhance their revenue as a result of Medicare Part D by using the program as a marketing opportunity to attract new patients. There are opportunities available by providing medication therapy management services (MTMS) and benefiting from improved patient outcomes as a result of increased access to medications.
- Practices can limit the expense of navigating the appeals and exceptions procedures through the development of efficient and effective processes within their practices to handle these matters.

supply coverage for benzodiazepines. Other legislation has been proposed to encourage enrollment and correct for mistakes in enrollment by delaying the late enrollment penalty and offering protection for beneficiaries against bad choices. These may include not only enrolling in the wrong plan, but also mistakenly disenrolling beneficiaries from their employer-provided retiree benefit. This bill would expand the existing open enrollment period from May 15, 2006 to the entire 2006 calendar year. It is hoped that this added time will give seniors the opportunity to perform research and make the best decisions for themselves. This bill would also give every person with Medicare the opportunity to make a one-time change in plan enrollment at any point during 2006. This would correct for any mistake made during the first year of implementation, which includes decisions that are based on incorrect www.Medicare.gov postings. The last provision would protect beneficiaries from being dropped by their former employer's plan dur-

ing the first year of implementation so that they have time to correct enrollment mistakes.

Now that the federal government is the largest purchaser of medications, we can expect continued pressure to prevent pharmaceutical pull-through. As one can imagine, the federal government will want to prevent any action that encourages the inappropriate use of medications. Currently, pharmaceutical pull-through strategy is implemented to encourage the use of a particular product, which sometimes results in prescriptions being written for inappropriate patients. As a result of the belief that federal funds might inadvertently be used to pay for inappropriate care, the federal government has stated that where a manufacturer offers subsidies tied to the use of their products, the subsidies are subject to all of the usual penalties of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs, increasing costs to Medicare, providing a financial advantage over competing drugs, and reducing beneficiaries' incen-

tives to locate and use less expensive, equally effective drugs. This principle, while originally aimed at pharmaceutical patient assistance programs and rebates provided to long-term care pharmacies, can easily be applied to drug sampling and direct-to-consumer advertising. Expect this sentiment to grow and result in significant restrictions in how pharmaceutical marketers educate about, and provide pull-through of, their products.

In the End

Rather than simply modernizing Medicare, a more thoughtful process would be to focus on continuous quality improvement in which clinicians lead the way to system redesigns that optimize outcomes. The history of changes to Medicare demonstrates that this has not been an easy path. The most recent previous attempts include the catastrophic Medicare bill of 1986 and the Clinton health care plan of 1993, both of which lacked clinician involvement and failed implementation. Clearly, while today is very different than yesterday, tomorrow promises to be even more different than today. Hopefully, Medicare providers will play an active role to ensure that what is different is also considerably better for our patients.

Resources

www.Medicare.gov

This link provides access to a comparison of all prescription plans that are available to beneficiaries living in a specific zip code. It ranks the plans from the least to the most expensive, based on a comparison of up to 25 medications.

www.ssa.gov or www.shiptalk.org

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