The Medicare Modernization Act (MMA): How Will It Affect P&T Committee Members?

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There is a great deal of confusion surrounding the Medicare Modernization Act (MMA), formerly known as the Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA). Stephen Barlas touched upon the complexity of this topic in his recent column in P&T. In his article, he illustrated that even the writers of this legislation don’t understand how it will be implemented. The issues involved will have major implications for all Americans, especially for P&T committee members, for decades to come.

As Mr. Barlas pointed out, one primary point of confusion involves the number of medications that will be needed to meet the formulary requirement. Although the legislation does say that a formulary must include “drugs” within each therapeutic category and class, it is unclear whether this means only one drug, which currently applies to the Medicare Prescription Drug Discount Card, or more than one drug for the “Part D” Medicare Prescription Benefit. As you can imagine, the difference between “one” and “two” (or more) has important repercussions for patients and pharmaceutical companies.

In addition, the design of these formularies is dependent on the therapeutic categories and classes that are chosen. The United States Pharmacopeia, in consultation with pharmacy benefit managers (PBMs), is designating these therapeutic categories and classes. The strength of these formularies is still very much in question, because MMA allows physicians to override formularies if they believe that nonformulary medications are medically necessary.

Still unanswered are the questions of how the appeals process might work and how much strength will be given to the plans in enforcing their formularies. The oversight of these formularies, as well as the appeals process governing nonformulary medication use, will be the responsibility of the plans’ P&T committees. The requirements for P&T committees have changed from those in the legislation passed by the Senate in June 2003. At that time, the Senate required P&T committees to include an academic expert; however, the final legislation removed this requirement. The current law simply states that prescription drug plans (PDPs) that include formularies must have P&T committees and that the majority of members on the committees must be practicing pharmacists and physicians with expertise in geriatrics.

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MEDICARE PHARMACY BENEFIT

The basic Medicare pharmacy benefit calls for a premium of $35 per month with an initial $250 deductible, after which the benefit starts by providing 75% coverage for medications costing between $250 and $2,250. This coverage costs $500 for the benefit between $250 and $2,250. This amount, when added to the annual premium of $420 and the deductible of $250, means that a senior citizen will pay $1,170 for $2,250 worth of medications minus any additional discounts. After this point, the “donut hole” kicks in; the beneficiaries will be responsible for 100% of charges until their total out-of-pocket costs reach $5,600. At this point, the “catastrophic coverage” applies and the beneficiaries are responsible for only 5% with no limit.

In addition to this standard benefit, three low-income beneficiary plans are available, depending on the beneficiary’s income level. These voluntary benefits are to be administered not by the federal Medicare program directly but by PDPs, either through traditional fee-for-service (FFS) Medicare or by Medicare managed care plans. This is in keeping with the MMA philosophy of staying far away from price controls or other controls that might otherwise reduce the pharmaceutical industry’s ability to negotiate prices.

AARP (formerly, the American Association of Retired Persons) and others anticipate that although this program is voluntary, most senior citizens will participate because of their aversion to risk and because of the late-enrollment penalty applied to those who wait to join until they truly need to benefit. Because this new benefit will involve many older adults, there is great concern that employee-based plans might drop their coverage for retirees; as a result, MMA provides an incentive for these plans to continue.

To encourage employers to maintain their retiree PDPs, plans that offer actuarially equivalent coverage will receive a 28% payment for drug costs between $250 and $5,000. This subsidy is excluded from taxation. P&T committee members should note that these qualified retiree plans, unlike the Medicare PDPs, will have maximum flexibility in their design, formularies, and networks.

Another outcome of the pharmacy benefit is the inclusion of the “dual eligibles” under the new Part D Medicare benefit. “Dual eligibles” refers to the 6.2 million American senior citizens whose health care costs are covered by both Medicare and Medicaid. Most observers of this legislative process were truly surprised that the dual eligibles were addressed. Despite the Bush administration’s position against inclusion of this group, the states won out because of their inclusion in the Medicare Part D benefit. This has significant implications for states whose responsibility for this group will now, for the most part, be eliminated. Unfortunately for the states, they will

Vol. 29  No. 2 • February 2004  •  P&T. 95
have to develop a process to coordinate benefits so that their State Pharmaceutical Assistance Programs (SPAPs) become compatible with the new Medicare Prescription Program.

A direct effect of including the dual eligibles will be felt especially in New York State, where nursing facilities will be relieved of the financial risk of medication management. New York is currently the only state to require nursing homes to be financially responsible for a significant portion of their Medicaid residents’ pharmacy expenditures. Because New York’s Medicaid program will no longer be liable, this responsibility will not continue to be passed along to the nursing homes through a capitation arrangement. Instead, it is likely that New York’s nursing facilities will be treated like all other nursing homes and will be financially responsible only for medications for those skilled residents under the Medicare Prospective Payment System.

The primary concern raised by these changes is one of access—specifically how to maintain the relationship between long-term-care residents and their long-term-care pharmacy providers. MMA lays the foundation for an answer by providing standards with respect to access for enrollees who are residing in long-term care facilities. The need for specific access in long-term care is based, in part, on federal regulations that require such facilities to adhere to specific pharmacy requirements that exceed those of the community pharmacy. As a result of these regulations, as well as state regulations and the standards of practice that govern long-term care, specialized long-term-care pharmacy providers—rather than community pharmacies—provide the medications to long-term-care residents. Because of these mandates, which are based on quality-of-care concerns, it is necessary for long-term-care residents to receive their medications through the one long-term-care institutional pharmacy provider that has contracted with their facility. It is expected that MMA regulators will provide appropriate access not only to beneficiaries residing in long-term-care facilities but also to those in Indian Health Services and the U.S. territories, all of which are mentioned in long-term-care facilities but also to those in Indian Health Services and the U.S. territories, all of which are mentioned for special consideration in the legislation.

Effective January 2006, Medigap plans will provide a supplemental health benefit that includes a prescription drug benefit. As a result, elderly people will have to obtain their prescription benefit through either a fee-for-service PDP (FFS–PDP), a Medicare Advantage PDP (MA–PDP), or an employee plan. To ensure that Medicare beneficiaries have access to a prescription plan, Medicare will encourage the development of MA plans in all regions. A $12 billion stabilization fund is intended to provide financial motivation for plans to become available in some of the less lucrative regions, such as in rural areas and in locales with lower Medicare managed care reimbursement rates.

To ensure that FFS–PDPs exist in all areas, the Centers for Medicare & Medicaid Services (CMS) is authorized to develop private fallback plans. These plans will be operated by organizations in the private sector under less of a risk-bearing model and more of a traditional PBMs model of administrative fees. Organizations that have made bids to become risk-bearing entities cannot become fallback plans. This restriction will limit the number of organizations that may participate as fallback plans and, as a result, will make it difficult to find eligible organizations to become fallback plans.

Although the Medicare Prescription Benefit does not go into effect until January 1, 2006, Medicare beneficiaries will receive some immediate relief with the introduction of the Medicare-endorsed Drug Discount Card. Beneficiaries may apply for these cards starting in May 2004, and the program begins the following month. This card will cease to exist when the Medicare Part D benefit is introduced on January 1, 2006. The discount cards are expected to provide a 20% reduction over market rates. The true benefit of this program accrues to low-income individuals, who will receive $600 annually toward their medication expenses. Known as the Transitional Assistance Program, it bridges the gap leading to the full Medicare Drug Benefit, which offers enhanced benefits for low-income senior citizens.

Despite the strength of the State Pharmaceutical Assistance Programs to provide this benefit, the states are specifically excluded from participating. As noted in the legislation, a card sponsor can be any "nongovernmental" entity that the Secretary determines is appropriate to offer an endorsed discount card program. This is another move directed to maintain the pharmaceutical industry’s ability to negotiate prices with small entities instead of having prices dictated to them by large oligopolies.

P&T committees are sure to play a crucial role in ensuring optimal cost management and quality assurance within each of the hundred PDPs to be developed as a result of MMA. PDPs must establish programs for medication therapy management in consultation with pharmacies and physicians and will need to provide reimbursement for these services that take into account their costs. These programs must be designed to ensure that drugs are appropriately prescribed to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. Not surprisingly, targeted individuals are those with multiple chronic diseases, those who are taking multiple drugs, and those likely to incur annual costs that exceed a specified level.

MMA also requires CMS to contract with the Institute of Medicine to conduct a comprehensive study of drug safety and quality issues to provide a plan for systemwide changes to produce quality improvement.

In addition to the increased responsibilities of P&T committees under MMA, prescribers must also ensure that an e-prescribing system will be in place by April 2009. In addition, prescribers will be transferring prescription information and PDPs will be providing them with information on members’ eligibility, benefit information, formulary structure, and beneficiaries’ medical histories. Through an e-prescribing system, it is hoped that medication errors will be reduced and that medications will be used more appropriately. To help facilitate this goal, CMS is providing grants to physicians to develop these systems and MA plans are being encouraged to provide financial incentives to prescribers who use e-prescribing systems to their full potential.

In an additional effort to provide for cost savings in the Medicare program, PDP enrollees will be informed at the time of purchase of any differential between the price of the agent prescribed and the price of the lowest-cost generic drug that is therapeutically equivalent and bioequivalent. With this type
of information available, it is hoped that enrollees will become more adept at choosing lower-cost alternatives.

Perhaps the strongest provision in the effort to lower prescription costs is MMA’s elimination of loopholes in the Hatch–Waxman Act. This regulation addresses ways to speed the introduction of generic drugs to market, thereby giving patients lower-cost alternatives. This provision will probably have a much greater impact than MMA’s authorization to allow the reimportation of drugs from Canada if the Secretary of Health and Human Services acknowledges their safety and need. Given that Congress had previously authorized drug reimportation from all industrial countries and that the Secretary has never implemented the provision because of safety concerns, it is unlikely that we will ever see medications arriving from Canada. For more on the Hatch–Waxman Act, see Marvin Goldenberg’s article on page 89.

**MEDICARE ADVANTAGE**

Medicare Advantage (MA) will replace the Medicare + Choice (M + C) program. In addition to the name change to the plans will be the development of many regional Preferred Provider Organizations (PPOs) as well as increases in their reimbursement. The concern is that increased competition from PPOs, as well as future cuts in reimbursement resulting from tight budgets, will make M + C organizations unprofitable. The current process of reimbursing M + Cs according to *adjusted community rates* will be replaced in 2006 by a plan-bidding process.

If MA plans continue to exist, they will be required to provide PDPs for their enrollees. They cannot be MA-only plans; they must be MA–PDP plans. It is expected that the number of Medicare beneficiaries being served by MA plans, which include both M + C and PPO plans, will increase because of the ability of the plans to enhance their benefit packages and to cover regions previously devoid of managed care coverage. Besides receiving MA plans, beneficiaries will be able to receive pharmacy Part D benefits from PDP programs that operate independently of MA plans for those beneficiaries in the traditional FFS Medicare program.

Under MMA, specialized MA plans will also be permitted; an example is United Healthcare’s EverCare, which serves nursing-home residents. These plans must exclusively serve beneficiaries with special needs. Special-needs beneficiaries are MA enrollees who are institutionalized or who are entitled to Medicaid or are individuals with severe and disabling conditions that the Secretary deems would benefit from a dedicated plan. As in most cases with the Program for All-inclusive Care for Elderly (PACE), these specialized MA plans will probably create their own P&T committees, given the significant pharmaceutical needs of the plan’s members.

**OTHER PROVISIONS**

Besides the Medicare pharmacy benefit, beneficiaries will also have access to more disease-prevention services, including an initial physical examination, cardiovascular and diabetes screening, blood tests, and enhanced mammography benefits.

Providers would also be positively affected; many MMA provisions would generally increase FFS payments within Medicare’s “Part A” and “Part B” programs, especially for rural health care providers. Many other regulatory and administrative practices would also be modified.

Despite the overall positive benefits of MMA, however, some health care providers might be adversely affected, especially those who have profited from high reimbursements for medications under Part B. This is especially true for oncologists and other physicians who bill Medicare for drugs that they purchase. Specifically, many covered outpatient drugs furnished in 2004 will be reimbursed at 85% of the average wholesale price (AWP). Then, starting in 2005, Medicare’s payment for many covered Part B outpatient drugs will be based on an average sales price rather than the much higher AWP. This negative impact should be offset, to some degree, by an increase in practice expenses for free-standing oncology centers that administer chemotherapy and for physicians who routinely offer injections in their offices. The exact financial effect of these changes on individual providers will vary, depending on factors such as the characteristics of the enrollees or entities participating in Medicare and the number and type of Medicare services provided.

**FUTURE DIRECTIONS**

Perhaps we can get a sense of what can be expected from the Medicare pharmacy benefit by considering how durable medical equipment (DME) is being treated. DME providers may also experience negative changes in their payment rates over the next several years. A DME competitive bidding process will be phased in to include all DME, home infusion and home oxygen systems, and off-the-shelf orthotics.

The trigger for price regulation for the pharmaceutical industry will come when the Medicare trustees report indicates to the President the existence of a funding warning. At that point, the President is required to submit a proposal to Congress to make alterations in the Medicare program to ensure its continued viability.

The response will probably be the same as in the past—one of reduced reimbursement. This is what has been occurring with physicians and other providers who are now contending with price controls under Medicare. Whatever the future holds, it is clear that P&T committee members will have the opportunity to play a critical role in ensuring optimal medications and therapeutic management for senior citizens for years to come.

**REFERENCES**


**SELECTED READINGS**

