

Gail R. Wilensky

### implementing the MMA

A lot has been written about the adequacy of the drug benefit in the new Medicare Prescription Drug, Improvement, and Modernization Act (MMA) and the political arm-twisting needed to get the legislation through Congress.

More recently, considerable attention has also been focused on the \$134 billion discrepancy in the 10-year cost estimates of the legislation that comes from comparing the Congressional Budget Office's estimate of \$400 billion with the Bush administration's budget submission estimate of \$534 billion. Very little has been written about the enormity of the challenges facing CMS in terms of implementing this new legislation.

Although the MMA's primary focus is on providing a new drug benefit and on encouraging private plan participation in Medicare, the bill also contains changes to many other parts of Medicare. The most important of these include major and minor changes to Part B outpatient drug coverage, a variety of changes to Medicare provider payments, and a variety of studies relating to benefits or provider payment changes or other new beneficiary benefits under Medicare.

Many people have complained about the January 1, 2006, start date of the Part D benefit. However, a large number of operational decisions need to be made and implementing regulations need to be issued before November 15, 2005—the date when current Medicare beneficiaries are scheduled to begin their enrollment for the new benefit.

The legislation itself acknowledges this burden by making available \$1 billion to CMS to support the implementation process and by providing the Social Security Administration with \$500 million

for use in determining which senior citizens have incomes low enough to qualify for special low-income subsidies in the bill.

All of this work needs to occur during a period when there has been an unusually high level of turnover in the senior career staff of CMS. Fortunately, with the recent confirmation of Mark McClellan as the new CMS administrator, the agency will not have to initiate this activity under interim leadership.

### Implementing the major provisions of the MMA will take a Herculean effort by CMS.

#### Implementation Challenges

CMS faces many significant implementation challenges associated with the MMA. Chief among these involve implementation of provisions pertaining to private prescription drug plans (PDPs), Medicare Advantage, and Part B outpatient drug coverage.

*PDPs.* Under the MMA, the new drug benefit can be provided either by a risk-assuming private PDP or as part of a comprehensive benefit provided by a private health plan. A significant challenge for CMS is that neither the agency nor the private sector has any experience with PDPs. Presumably, the PDPs will come mostly from existing pharmacy benefit managers (PBMs) or private insurance plans, but they will need to be licensed by their respective states before they

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can begin negotiating with drug manufacturers or establishing formularies.

Examples of the decisions and rulemaking that will be required to make PDPs operational include establishing:

- > Actuarially equivalent drug-benefit packages
- > A bidding process for selecting and pricing the plans
- > Premium subsidies and risk corridors around the bids
- > Rules outlining contingency plans should fewer than two private-sector plans submit bids in a region

*Medicare Advantage.* The legislative language of the MMA does not completely explain how CMS is to substitute the Medicare Advantage program for the Medicare+Choice program, established by the Balanced Budget Act of 1997. The law describes many of the changes that will be required, but other changes will need to be described through regulation. For example, CMS has yet to define the number and size of the regions used for plan participation, the bidding process that will take effect in 2006, and the negotiating process to be used by the government around the bidding process.

*Part B outpatient drug coverage.* Changes to the existing Part B outpatient drug coverage pose another major administrative and implementation challenge in the MMA. Part B drugs will be paid under the same average-wholesale-price (AWP) methodology that has been used for the last 30 years but at a lower percentage of AWP. Starting in 2005, most Part B drug payment will be based on average sales price (ASP) rather than AWP. The biggest change in Part B drug payments

will occur in 2006, when physicians choose whether to continue receiving payment for Part B drugs based on ASP or to turn over the purchasing process to a competitive acquisition-pricing strategy.

All of these changes will compound the difficulties for CMS. Accurate payment will require accurate reporting of ASP, the Medicaid rebate best price, and the average manufacturer price. Particularly challenging will be establishing the competitive acquisition methodology. To have this option available to physicians by 2006, CMS will need to have the methodology (and associated regulations) in place by 2005. Because the MMA requires that there be at least two contractors in each geographic area, CMS will need to clearly define the geographic areas, establish appropriate quality and access standards, and determine the financial stability and solvency standards that should be imposed on the bidders.

### Early Results

Despite the daunting challenges CMS faces, the early results have been promising. The regulations defining the drug discount card were issued shortly after the legislation was signed, and the response by sponsoring organizations has been promising. CMS has also recently released the ASP regulation that will be used next year for Part B drugs.

Implementing the major provisions of the MMA will take a Herculean effort by CMS. It is important for Congress and the public to understand that any substantive changes to the legislation now—either altering the decisions required to make the law operational or forcing a change in the implementing regulations—will make it extremely difficult, if not impossible for the drug benefit to commence in January 2006. Such an outcome may be acceptable to individuals who believe the legislation is fundamentally flawed, but for the individuals who will depend on the benefit, waiting for it any longer may become unbearable. ●

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