With a deadline of June 1, 2004, looming for the beginning of the Medicare Prescription Drug Plan (PDP) Discount Card program, a consortium of more than 30 organizations co-sponsored the National Medicare Prescription Drug Congress on Capitol Hill in Washington, DC, from February 25–27, 2004. The main objective was to assess the various areas of health care that will be affected by the new Medicare Modernization Act (MMA), formerly called the Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA).

Major goals of the congress were to summarize the new legislation (including the Drug Discount Card program); to explain its implementation and time frame, as set forth by the Centers for Medicare & Medicaid Services (CMS) and for the Food and Drug Administration (FDA); and to discuss the effect of the MMA on pharmaceutical manufacturers, health insurance plans, pharmacy benefit management (PBM) companies, state Medicaid plans, and health care professionals.

The three-day meeting featured many health care experts from various government and private sectors. This article summarizes the main perspectives of the congress as echoed by six selected speakers from different areas of health care:

• The Honorable Tommy Thompson, Secretary of the Department of Health and Human Services (DHHS)
• Thomas Scully, former administrator of the CMS
• Mark McClellan, FDA Commissioner
• Governor Dirk Kempthorne of the state of Idaho
• Fred Hassan, Chairman and Chief Executive Officer of Schering-Plough Corporation
• Barrett Toan, President and Chief Executive Officer of Express Scripts

The DHHS Perspective

On the first day of the meeting, Secretary Tommy Thompson discussed the impact of the MMA on health care from the DHHS perspective. He began by stating:

“It [Medicare] was a law that needed to be updated. It is not perfect, but it needed to be done.”

He pointed out that the MMA will foster medical advancement for American senior citizens and that it will subsequently improve access to health care and will enable preventive disease management.

According to DHHS estimates, two million Medicare Advantage recipients (formerly Medicare Plus Choice) will be paying lower premiums via cost sharing. Approximately another 3.4 million people will receive enhanced benefits, as the existing 32% of beneficiaries who currently have coverage for brand-name prescription medications is expected to rise to 45%.

Mr. Thompson emphasized that the MMA will add “transparency to the prescription drug market” because the prices of medications will be listed and updated regularly on the
improperly stored, not fit for human consumption, or in violation of other FDA medication laws. As a result, he stated that the DHHS would set up a commission with the FDA to study the practice of re-importation and to report to Congress by December 1, 2004, on whether and how it could be accomplished. (For more on this topic, see “The FDA Perspective” on the next page.)

The CMS Perspective

Thomas Scully, former CMS administrator, gave several examples “from the battlefield” of the prescription drug legislation and its potential impact on American senior citizens and health care in general. He touted the MMA as “the deal of the century and millennium” and as a “spectacular deal for rich and poor seniors.”

He noted that Medicare will cover approximately 41 million senior citizens. Of these, 11 million are poor and have no drug coverage and 10 million have Medigap coverage; both groups will be transferred over to the new Medicare plan under the MMA. In addition, the coverage of the so-called “dual eligibles” (those eligible for both Medicare and Medicaid) will be shifted from the states to the federal government under the MMA.

According to Mr. Scully, all of these shifts will give Medicare approximately 50% of the prescription drug market and will force price competition. He envisions that the creation of these

Table 1  Low-Income Benefit Packages

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Monthly Premium</th>
<th>Medicare Coverage</th>
<th>Co-pay</th>
<th>Gaps in Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>135% below federal poverty level*</td>
<td>$0</td>
<td>Partial coverage; no deductible</td>
<td>$2 for generic drugs and $5 for brand-name products; up to $3,600 out-of-pocket limit, then $0</td>
<td>None</td>
</tr>
<tr>
<td>135%–150% below federal poverty level†</td>
<td>Sliding scale‡</td>
<td>Partial coverage; $50 deductible</td>
<td>$2 for generic drugs and $5 for brand-name drugs; 15% up to $3,600 out-of-pocket limit</td>
<td>None</td>
</tr>
</tbody>
</table>

* $12,123 for individuals, $16,362 for couples.
† $13,470 for individuals, $18,180 for couples.
‡ Approximately $35 for 150% below poverty level.

Data from the Department of Health and Human Services. Available at: www.hhs.gov.
“purchasing pools” will enable the senior population to use their clout to lower prices through their insurance companies (specifically PBMs). This is the government’s attempt to curb growing health care prices and to enable coverage for more of the elderly poor. For pharmaceutical manufacturers that do not yet have CMS on their radar screens, Medicare will become the dominant force in their industry; in the CMS, however, a whole new entity will need to be created to regulate coverage of medications.

Because not all plans fit all seniors, the MMA will give the elderly the ability to pick hybrid plans, either health maintenance organizations (HMOs) or preferred provider organizations (PPOs). Hence, participants will be able to tailor their health care plans to their individual needs, and coverage will become uniform for the entire senior population. These changes, in turn, should encourage marketplace competition and dissemination of consumer information.

Mr. Scully suggested that the MMA is being created in order to provide incentives to third-party health care plans (such as PBMs) that have been subcontractors, primarily, under insurance plans but that have not been risk-bearing entities. He thinks that by enabling these PBMs to become PDPs for seniors, they will become free-standing parties that will drive the prescription drug market and will potentially improve quality through their medication-review initiatives.

The States’ Perspective
Governor Kempthorne voiced the concerns of the state legislatures from his experiences interacting with other governors as chairman of the National Governors Association. He emphasized that our system of reimbursement still rewards providers on the basis of treatment, not prevention. He stated:

“There is no profit in health, there is profit in disease. We need to incentivize health care professionals for preventative care.”

He mentioned that physical examinations, which would be mandatory for all Medicare enrollees, will become a critical component of identifying preventable chronic diseases. This “early identification and treatment,” it is hoped, would enable the postponement of disease and disabilities for many Medicare-eligible senior citizens.

The governor also spoke about the financial burdens of the states over the past four years. The states have seen the worst financial conditions since World War II because concerns such as terrorism, corporate scandals, the stock market downturn, and declining economic growth and consumer confidence, among others, have contributed to decreased funding for state budgets. Conversely, health care costs, particularly Medicaid expenditures for the states, have continued to rise.

As a result of financial strain on state budgets from these spiraling Medicaid costs, he envisions that budgetary issues might inevitably force a competition between education and health care in state budgets, creating a paradoxical situation of grandparents competing with grandchildren for state funding. It is hoped that the MMA will help to avert this dilemma for the states, because it should alleviate an estimated $17.2 billion over a 10-year period, according to the Congressional Budget Office (CBO).

The CBO expects about six million Medicaid patients to be switched over to Medicare by 2006 but also expects increases in state budgets in certain time frames within those 10 years. More frequent screening of patients, new resource utilization, and the increased coverage for people who fall 150% below the poverty line will raise the overall cost to states by approximately $1 billion between 2004 and 2006. Despite these setbacks, the governor sees MMA as having a positive and lasting effect on health care for older people in the U.S.

The FDA Perspective
The second day of the conference continued with more government perspectives on the effect of the MMA. FDA Commissioner Mark McClellan, newly nominated by President George W. Bush to head the CMS, stated that many senior citizens are considering gambling on the safety and effectiveness of their medications (i.e., buying re-imported medications) because they have grown tired of skipping doses and cutting pills. In essence, it has become a battle between safety and affordability. As stated earlier, the FDA cannot ensure the safety of medications ordered from outside the U.S. Dr. McClellan notes that the FDA has the duty to verify safety and the opportunity to lower drug costs while maintaining the integrity and legality of medications. Although Americans pay for half of the cost of all prescription drugs worldwide, the FDA is not sure whether it can certify that these medications are pure.

Like DHHS Secretary Thompson, Dr. McClellan cited a series of single pre-announced inspections of eight Internet pharmacies in Canada by FDA officials in Minnesota. The inspectors discovered widespread evidence of dozens of infractions, such as improper supervision by a pharmacist, improper storage of drugs, and labeling irregularities—“a true buyer-beware type of practice.” He also discussed the recently announced Wisconsin Web site for Canadian pharmacies, which describes, through various legal disclaimers, that the state of Wisconsin is not responsible for the practices or safety of the pharmacies listed on its Web site.

In order to answer how and under what circumstances re-importation can work, the FDA has established a task force that will hold at least five meetings to determine the viewpoints of a wide variety of stakeholders and the general public. The task force will comprise consumer groups, professional health associations, health care purchasers (employer groups, cities, and states), industry associations, and international stakeholders. In addition, open public meetings will be held to enable the general public to provide comments; there will also be an open public docket to accept comments on drug re-importation. All findings will then be presented publicly at a date to be determined.

Besides the re-importation issues, Dr. McClellan noted other attempts by the FDA to keep drug prices down, including the creation of larger generic drug programs and enhanced information technology. New reforms are being created to promote generic competition as soon as generic drugs are available. Citing CMS data, he said that the states spend 7% to 8% of their budgets for prescription drugs through Medicaid on medications that already have generic alternatives. He mentioned that in Illinois, 12 of 90 medications that are intended to be re-imported already have generics available that are
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less expensive than the brands that the state wants to import from Canada. The use of over-the-counter medications might be a way of lowering drug costs by as much as 30%.

He envisioned numerous initiatives by the FDA that should help reduce the costs of new medications but explained the difficulty of closing the gap when health insurance does not keep up with technology. Even with the advent of novel medications through new technologies, he believes that many American seniors cannot afford their prescribed medications.

Dr. McClellan thinks that technology improvements through electronic medical records are just around the corner because of the recent mandate of bar coding for all medications; however, the purchase of scanners to read the bar codes has not been mandated. (For more on this topic, see Stephen Barlas’ article on page 211.) Electronic prescribing (eRx) will enable information at the point of care to allow physicians to offer accurate dosing that will avoid drug interactions and side effects and to prescribe medications appropriately.

The FDA has several initiatives to encourage electronic prescribing in addition to the provisions outlined in the MMA for demonstration projects on the subject. A new electronic label will be created to allow digital updating of medications daily. This information will build upon current pharmacy databases so that prescriptions can be reviewed more quickly and accurately.

Nevertheless, Dr. McClellan points out that these systems are only as good as the information that is placed into them. The challenge of the MMA will be to create, implement, and use this technology to benefit older adults as well as patients of all ages.

The Drug Manufacturers’ Perspective

The rest of the second day, conference topics shifted from government perspectives to the effect of the MMA on various private stakeholders. Representatives from pharmaceutical manufacturers, health insurance plans, PBMs, large purchasers of health care, health care providers, and pharmacists talked about how the bill would change their respective practices and the challenges that all of them would face with respect to the MMA.

Fred Hassan of Schering-Plough touted the MMA as an accomplishment that will bring many opportunities and challenges to the pharmaceutical industry. He is encouraged by three major points of the legislation:

• The MMA will bring cost savings and discounts via cost-sharing mechanisms to millions of Americans.
• It will cap catastrophic expenditures for senior citizens.
• The MMA will shore up retiree programs, which have been decreasing over the past decade.

Mr. Hassan thinks that the legislation is not a government handout to the pharmaceutical industry; instead, it will create a “challenging purchasing environment” that will be difficult for manufacturers but that will provide much needed medications and integration of care for America’s senior citizens. The provisions on preventive care will improve the health of the elderly and will reduce expenditures.

He proposed that a National Charitable Medicine Foundation be established to streamline pharmaceutical manufacturers’ assistance programs. This foundation would provide one entry and one eligibility clearinghouse for all manufacturer-sponsored patient assistance programs. This would be an independent entity that would simplify the arduous process of applying for free medications from manufacturers and would encourage generic drug manufacturers to become involved to help in the cause as well.

He also advocated the establishment of a consortium of insurance companies to create a secondary insurance market of small coverage groups (similar to that of “Fannie Mae” in the mortgage industry), which would pool demographically diverse groups just as large employers can. This type of health insurance would allow greater coverage, access, and affordability to many of America’s uninsured citizens.

The PBM Perspective

Barrett Toan of Express Scripts, speaking for the PBM sector, proposed that PBMs would have to assume risks for utilization and management of medications but that cost savings negotiated between drug manufacturers and PBMs would result in more competitive pricing, thus leading to less expensive medications for older people. He advocated the use of mail-order pharmacies, formularies, substitution of generic drugs, and prior authorization as the way to achieve these savings, which would allow patients to receive meaningful discounts.

He suggested that the expanding role of PBMs through the MMA would lead to fewer employer liabilities because more employer groups would not have to cover as many medications for their senior and retired workers. Instead, the government would pay for a large part of these expenditures.

Conclusion

The utilization of prescription drugs will almost certainly increase as a result of the MMA. Consequently, many stakeholders—primarily government, industry, the senior population, and health professionals—will be affected. The congress covered many of these perspectives, but only a few could be mentioned in this article. Nevertheless, one thing is certain: the MMA legislation will affect all segments of health care in the U.S.

As many of the speakers at this meeting agreed, the impact of the legislation seems to be pointing us in the right direction, but the effects of this legislation are still unclear at this early stage. The scope of the MMA encompasses more than just an attempt to contain double-digit growth of health care expenditures. It takes a step in the right direction by offering patients preventive care; a continuum of care; and, most important, the option of prescription drug coverage. For these reasons alone, the MMA may prove to be worthwhile.

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