

# The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Implications for health-system pharmacy

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Am J Health-Syst Pharm. 2004; 61:1042-51

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*The Law Notes section analyzes laws and regulations that affect pharmacy practice in hospitals and health systems. Submissions and suggestions for topics should be sent to AJHP, 7272 Wisconsin Avenue, Bethesda, MD 20814 (301-657-3000, ext. 1200) or ajhp@ashp.org.*

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**O**n December 8, 2003, President George W. Bush signed into law the most sweeping change to the Medicare program since its inception in 1965: the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).<sup>1,2</sup> After several Medicare reform attempts in the late 1980s and 1990s, Republicans in Congress, with prodding from the Bush administration, finally acted without extensive delay or debate.

Several factors converged to bring this legislation into reality.<sup>3</sup> Demographic indicators pointed to the impending entrance of the baby boomers into the ranks of Medicare beneficiaries. President Bush needed to fulfill a campaign promise from the 2000 election as his 2004 reelection campaign loomed closer. Passage of a Medicare reform bill seemed imperative for the GOP to remain the majority in Congress. And enactment of major health legislation by the Republicans would, it was believed, help the GOP solidify a permanent shift of

the American electorate toward it on domestic issues.

Seniors had been clamoring for a prescription drug benefit so that the Medicare program could offer health benefits consistent with those received by working-age Americans. Also, health insurers, pharmacy benefit managers, pharmaceutical manufacturers, and large employers favored change now so that the benefit structure would remain profitable to them; prospects for this outcome seemed more likely under a GOP-controlled Congress.

The new law contains an immediate drug discount card endorsed by Medicare and prescription drug coverage that begins in 2006. It also contains provisions that will affect pharmacists, in particular pharmacists

who work in hospitals and other components of health systems. This article discusses the prescription drug discount card, the prescription drug coverage that begins in 2006, provisions that affect existing reimbursement and coverage for drugs covered by Medicare Part B, medications administered through the use of durable medical equipment, changes to the hospital outpatient prospective payment system (OPPS), and clarification for inpatient purchases by disproportionate-share hospitals participating in the Public Health Service's 340B program. The article also examines changes to the Hatch-Waxman Act that would speed generic drugs to market, provisions concerning importation of prescription drugs from Canada, and a provision that will include reimbursement for medication therapy management services in Medicare for the first time—a major victory for pharmacists.

## Overview of the new Medicare benefits

From the public's perspective, the most visible change that will result from the enactment of MMA is the addition of an outpatient prescription drug benefit. The pharmacy profession will be on the front line in administering this new benefit and therefore must have a solid understanding of the complexities, challenges, and opportunities it presents.

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The assistance of Gary C. Stein, Ph.D., and

review by William A. Zellmer, M.P.H., are acknowledged.

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MMA takes an important step forward by adding prescription drug coverage to the Medicare program and providing elderly patients access to vital medication therapy management services. There is an opportunity to improve the administration and oversight of drug benefits by promoting electronic prescribing and a standardized benefits card. However, this legislation creates immense challenges for pharmacists to ensure that private plan sponsors properly value and reimburse pharmacists' services. Also, implementing these benefits will be labor-intensive and time-consuming for the frontline practitioner, particularly with respect to helping beneficiaries understand the changes and maintain the continuity of care.

Many pharmacists have already begun receiving questions from Medicare beneficiaries. For example, when will prescription drug coverage begin? What drugs will be covered? Do beneficiaries have to enroll to obtain the new benefits? Will the changes affect their current coverage?

### **Medicare prescription drug discount-card and transitional assistance programs**

One of the first challenges the pharmacist faces is explaining to beneficiaries that the new Medicare outpatient prescription drug benefit does not begin until January 2006. Instead, in spring 2004, Medicare beneficiaries—except those enrolled in Medicaid and entitled to Medicaid drug coverage—will be able to enroll in a Medicare-endorsed, privately run prescription drug discount-card program. The discount-card program is intended to bring immediate relief to Medicare beneficiaries, who often pay the highest prices on the market for their medications. Participating seniors and disabled persons will be eligible to obtain discounts from pharmacies on their prescription medications. This discount card program will be phased out when

prescription drug coverage begins in 2006.

The Centers for Medicare and Medicaid Services (CMS) has acted with unprecedented speed to implement this program, with card sponsors scheduled to begin offering discounts to beneficiaries in June 2004. CMS estimates that beneficiaries who choose to enroll in a Medicare-endorsed discount card—for no more than \$30 annually—will garner savings of 10–15% on their total drug costs and 25% or more on individual prescriptions.

Private entities that have met the standards set by CMS, including mostly pharmacy benefit management companies and managed care health plans, have already been approved to offer a Medicare-endorsed discount-card program. Although beneficiaries will be allowed to enroll in only one Medicare-endorsed discount-card program at a time, they are guaranteed to have at least two choices of approved discount-card programs in each state. With 28 approved general discount card sponsors and many Medicare managed care plans that will also be able to offer drug discount cards to their members, it appears that beneficiaries will have many options.

Beneficiaries' selection of a discount-card program will have important implications regarding the medications that will be covered and their choice of a pharmacy. Each card sponsor can (and is likely to) create a formulary, as long as the formulary includes at least one drug from each of 209 therapeutic categories of drugs commonly needed by Medicare beneficiaries and at least 55% of these categories include a generic drug offered at a discount. These categories will be established through solicitations and published as a regulation.

Any pharmacy willing to accept the terms and conditions of the discount-card sponsor can participate in the discount-card program. However, card sponsors that ensure

an appropriate level of access to local pharmacies may set up a preferred network that would offer additional discounts to beneficiaries. Card sponsors cannot mandate the use of a mail-order pharmacy but can require beneficiaries to pay any price differential between the use of a mail-order pharmacy and a community pharmacy.

Information on discount-card sponsors' formularies and networks of pharmacies will be made publicly available. To maintain the continuity of care, it will be important for beneficiaries to understand these systems when selecting a discount-card program. The implications of the formulary and pharmacy networks are examined more extensively in the discussion of the comprehensive benefit.

The extent of the discount that each discount-card program offers is of obvious importance to beneficiaries in selecting a card. The CMS-projected discount is expected to result largely from rebates and other price concessions that card sponsors obtain from manufacturers. However, there is no explicit requirement that card sponsors pass these discounts on to beneficiaries. Instead, the competitive marketplace created by multiple card programs is anticipated to compel card sponsors to pass a substantial share of the discounts through to beneficiaries. Information regarding a card sponsor's negotiated price will be disclosed to the Secretary of Health and Human Services (HHS) and made publicly available to beneficiaries via a CMS Web site starting in spring 2004.

Pharmacists are likely to receive questions from beneficiaries about the discounts they offer. The availability of this information is a double-edged sword for each pharmacy. Beneficiaries will expect the lowest prices, even if these prices may not be available to the pharmacy or are available only through another Medicare-endorsed discount-card program. Once bene-

ficiaries select a Medicare-endorsed card, they can change programs only during an annual election period or under special circumstances, such as termination of a program or moving outside the service area of their current sponsor.

Because other private-sector drug discount cards already on the market, like the Pfizer Share Card, are permitted to continue without Medicare endorsement, beneficiaries may also inquire about which card provides them the best benefit. This could be a time-consuming question, depending on how many cards a beneficiary has in his or her pocket, particularly since the answer may be different for each medication the beneficiary needs. Also, the answer is likely to vary from week to week, since the prices of medications under the Medicare-endorsed card can change on a regular basis.

Pharmacies will also be on the front line explaining to Medicare beneficiaries a transitional assistance program for low-income beneficiaries to help them purchase their medications. Eligible low-income beneficiaries—individuals with an annual income of less than \$12,124 and married couples with an income of less than \$16,363—will qualify for a subsidy of up to \$600 a year, credited to their card, to use on prescription medications. Pharmacies will need systems in place for recording these transactions.

To the extent that the discount-card program has the potential to increase the affordability and accessibility of medications and preserve existing pharmacist–patient relationships, it is an important step on the path to Medicare prescription drug coverage in 2006. However, simply providing greater access to medications does not by itself ensure improved health outcomes. The elderly and disabled are among the highest-risk patients, often using multiple medications. They need access to pharmacists, professionals who have the expertise to ensure appropriate medication use. The discount-card program does not provide for increased access to medication therapy management services offered by pharmacists.

Considerable time and energy will go into implementing the drug discount program. While it is an interim measure that will be phased out when the 2006 benefit is implemented, it serves as Medicare’s stepping-stone to outpatient drug coverage. Many of the questions raised over the next few years will likely shape the 2006 benefit.

**Medicare prescription drug benefit**

As 2006 approaches, Medicare beneficiaries will face many difficult and confusing choices. First, beneficiaries will have to decide whether they even want to participate in the

new Medicare outpatient prescription drug benefit. This benefit, which is included in Medicare as a Part D benefit, is voluntary and includes a separate deductible and premium. This is in addition to what beneficiaries currently pay for Part B, which covers services provided by physicians and other recognized health care providers, home health care, and durable medical equipment. An overview of the components of Medicare can be found in Table 1.

A beneficiary’s decision about whether to enroll in the Medicare outpatient drug plan may be dependent on the beneficiary’s current coverage status. For example, does the beneficiary’s former or current employer provide coverage for the prescription medications? Has the beneficiary been obtaining prescription drug coverage through a state’s pharmaceutical assistance program? Will these options continue, and are they preferable to the Medicare coverage?

In many cases, beneficiaries’ current prescription drug coverage will be more generous than Medicare. However, the extent to which these alternative payers will continue to cover beneficiaries who are eligible for voluntary Part D coverage is uncertain. Congress intends to maintain coverage of many of the current payers by, for example, providing \$88 billion in direct subsidies and tax-related incentives to employers. Some state pharmaceutical assistance

Table 1.  
**Components of Medicare**

| Component                           | Eligibility for Enrollment   | Benefits   | Funding Source  |
|-------------------------------------|--|--|---|
| Part A                              | Entitlement for most people who are over 65 years of age or have end-stage renal disease | Inpatient hospital services, skilled-nursing facilities, home health visits after a hospital or skilled-nursing facility stay  | Payroll taxes held in the Hospital Insurance Trust Fund |
| Part B                              | Voluntary  | Physician and other outpatient hospital services   | Beneficiary premiums and general revenues               |
| Part C (renamed Medicare Advantage) | Voluntary  | Integrated Part A and Part B coverage through a managed care plan  | Combined funding  |
| Part D                              | Voluntary  | Any prescription drug, biological product, or insulin product covered by Medicaid and used for a medically accepted indication | Beneficiary premiums and general revenues               |

programs can also continue as an alternative to the Medicare plan. However, many employers and most of the state assistance programs are likely to use their limited dollars to supplement the Medicare benefit, such as by paying low-income beneficiaries' premiums or increasing the scope of coverage. Beneficiaries are likely to be confused as long-standing arrangements are disrupted and replaced by different packages, and the assistance of pharmacists in coordinating these benefits will be necessary.

The Medicare Part D benefit provides fairly limited coverage, acting more, for the average beneficiary, as insurance against catastrophic medication costs. Medicare beneficiaries, particularly those with low medication costs, may question whether they would actually save money by enrolling in this program.

The new law establishes a minimum standard prescription drug benefit that plans must offer. The

premium for the standard benefit is estimated to be \$35 per month (\$420 per year) for 2006 and will increase in subsequent years. Under the standard benefit, beneficiaries will pay a \$250 annual deductible for their prescription drugs, 25% of their annual drug costs from \$251 to \$2250, 100% of their annual drug costs from \$2251 to \$5100, and a copayment of \$2 for generic drugs and \$5 for brand-name prescriptions or 5% coinsurance, whichever is greater, for all drug costs above the catastrophic threshold of \$5100/yr. Low-income Medicare beneficiaries will have a more generous benefit available, with subsidized premiums and less cost sharing.

Figure 1 shows the cost sharing between Medicare and the beneficiary. The benefit structure, with its varied cost sharing, will be confusing to beneficiaries, particularly when they reach what is commonly referred to as the "donut hole" between drug

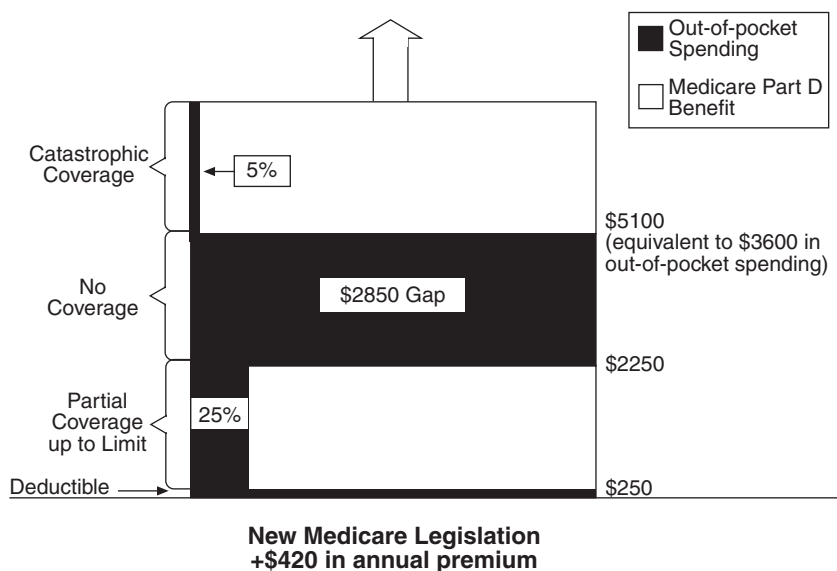
costs of \$2251 and \$5100 and pay 100% of their drug costs plus a monthly premium. CMS will make a significant effort over the next few years to educate beneficiaries about the scope of the coverage, but pharmacists will need to be ready to provide an explanation.

Once a beneficiary has decided to participate in the Medicare Part D benefit, he or she will still have several decisions. The drug benefit will be administered through a private entity, such as a health plan, an insurer, or a pharmacy benefit management company. The beneficiary may choose to remain in traditional Medicare and enroll in a stand-alone, add-on benefit or move from traditional Medicare to a managed care plan (like Medicare + Choice, now called Medicare Advantage) that will offer additional benefits beyond what is included in traditional Medicare.

All beneficiaries will have a choice between at least two plans in each region: at least one stand-alone prescription drug plan and one integrated plan (or two stand-alone prescription drug plans if no integrated plan is available). It is likely that each of these benefits will have different deductibles and cost-sharing amounts, have a different network of pharmacies, and cover different medications. Therefore, beneficiaries will need to carefully review the characteristics of each plan before choosing one to enroll in. Beneficiaries' choices will have definite implications, depending on their preferences in pharmacies and the medications they are taking.

**Access to a preferred pharmacy.** MMA is intended to preserve the continuity of care by requiring drug plan sponsors to allow the participation of "any willing pharmacy" that meets the terms and conditions established by the plan sponsor. The sponsor may establish among these participating pharmacies a preferred network through which it could offer beneficiaries a reduced copayment or

**Figure 1.** Out-of-pocket drug spending in 2006 for Medicare beneficiaries under the new Medicare legislation. Benefit levels are indexed to growth in per capita expenditures for covered Part D drugs. As a result, the Part D deductible is projected to increase from \$250 in 2006 to \$445 in 2013; the catastrophic threshold is projected to increase from \$5100 in 2006 to \$9066 in 2013. Reprinted, with permission, from "The Medicare Prescription Drug Law," the Henry J. Kaiser Family Foundation, March 2004. (The Kaiser Family Foundation is a nonprofit, independent, national health care philanthropy and is not associated with Kaiser Permanente or Kaiser Industries.) ([www.kff.org/medicare/medicarebenefitatan glance.cfm](http://www.kff.org/medicare/medicarebenefitatan glance.cfm)).



coinsurance for using an in-network pharmacy. This preferred network must include a sufficient number of local pharmacies to ensure convenient access by beneficiaries. The HHS Secretary must establish access rules for in-network pharmacies that are no more restrictive than those used currently in the Department of Defense TRICARE system. These standards require 90% of enrollees to have access to a community pharmacy within 2 miles in urban areas, 90% to have access to a community pharmacy within 5 miles in suburban areas, and 70% to have access to a pharmacy within 15 miles in rural areas.

Drug plan sponsors cannot require beneficiaries to obtain their medications through mail-order pharmacies. In fact, MMA ensures that beneficiaries can obtain the same prescriptions, including 90-day supplies of long-term medications, at their local pharmacy, although the insurer can pass on any added costs to the beneficiary.

This system (with its nonparticipating, participating, and in-network pharmacies) is likely to prove confusing to beneficiaries and providers alike. Health-system pharmacists, particularly if they are providing hospital discharge counseling to patients or working with a prescriber, are likely to receive questions about where beneficiaries should go to pick up their prescriptions. This information will likely be most accessible and up-to-date on each plan's Web site. Hospitals with an outpatient pharmacy will also need to determine whether they want to participate in or function as an in-network pharmacy.

**Covered medications.** In theory, Medicare prescription drug plans are required to cover all FDA-approved brand-name and generic prescription drugs, insulin and insulin syringes used for a medically accepted indication as defined under Medicaid, and smoking-cessation agents. However, at the same time, drug plans are permitted to use formular-

ies and create differential copayments to influence beneficiaries' drug choices.

Each plan sponsor that chooses to use a formulary will be required to establish a pharmacy and therapeutics (P&T) committee, which will include at least one practicing pharmacist, to develop and review the formulary. The process will be similar to that on the inpatient side, with the committee required to base clinical decisions on the medical literature. The formulary must have drugs within each therapeutic category and class covered under Medicare Part D, but not necessarily all drugs within such categories and classes.

The plan must have procedures in place for a beneficiary to appeal a denial of coverage if a prescribing physician deems the drug being denied is necessary for reasons of safety or efficacy. Removal of a drug from the formulary or a change in a drug's preferred status or copayment can take effect only after appropriate notice has been provided to the Secretary of HHS, beneficiaries, and practitioners.

The pharmacy that dispenses a covered drug is required to inform the beneficiary at the time of purchase (or at the time of delivery, in the case of mail order) of any price difference between the dispensed drug and the lowest-cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent and available at the pharmacy. It is unclear how the pharmacist will obtain this information, but doing so could be time-consuming.

While the development of formularies by each plan sponsor is not expected to have direct implications for formularies used on the inpatient side, the proliferation of formularies will present many challenges for hospital and health-system P&T committees and practitioners working to ensure coordination and continuity of care. It is, obviously, beneficial to start a patient on a course of treatment in

the hospital that will be covered when the patient leaves the hospital. This is not a new problem, particularly with the growing number of state Medicaid programs adopting preferred-drug lists and formularies, but it will require additional pharmacist time and resources to coordinate benefits and explain to patients why a non-covered medication is being used.

### Advancement of pharmacy practice

**Improving administrative efficiencies.** MMA includes several provisions intended to ease the burden on pharmacies participating in the outpatient drug benefit. For example, beneficiaries are guaranteed access to the drug plan sponsors' negotiated prices (including all discounts, direct or indirect subsidies, rebates, and other price concessions) at all times, even during the gap in coverage when no Medicare benefit is paid. To facilitate the transfer of this information, drug plan sponsors are required to issue a standardized benefits card to make it easier for the pharmacist at the point of sale to determine the price the beneficiary should be charged.

In addition, MMA encourages the use of electronic prescribing programs that will provide practitioners, on a real-time basis, with information for improving patient safety and quality of care and enhancing efficiencies, including cost savings. This information will include a patient's eligibility, benefits, and formulary drugs, as well as data on the prescribed drugs and other medicines the beneficiary has previously received. The electronic prescribing programs will allow beneficiaries to designate which pharmacy dispenses the drug, and medical histories related to covered medications will be transmitted to the pharmacist or to other health care professionals as requested.

Adoption of these electronic prescribing programs will be voluntary so as not to impose an undue admin-

istrative burden on prescribers and dispensing pharmacies. But information transferred electronically will have to meet federal standards developed by HHS in consultation with stakeholders, including hospitals, pharmacies, and pharmacists.

The standardized benefits card and electronic prescribing system have the potential to free up considerable pharmacist time and will provide important medication history information to pharmacists, allowing them to focus on medication therapy management services.

**Medication therapy management programs and other quality assurance measures.** MMA requires drug plan sponsors to advance several measures intended to improve medication use, including a drug-utilization management and quality assurance program and a medication therapy management program. The American Society of Health-System Pharmacists (ASHP) and the pharmacy community can and will play a substantial role in developing and implementing all of these programs.

The key distinction among these activities is the direct provider-to-patient interaction and care that characterize an effective medication therapy management program. By comparison, many existing drug-utilization management and quality assurance programs are population based. While MMA provides little guidance as to what the new programs should look like, CMS and drug plan sponsors are likely to adapt current standards of practice in prescription drug benefit designs, particularly with respect to drug-utilization management and quality assurance.

We are entering a new era in medication therapy management. This legislation is an important step forward for pharmacy. The recognition of medication therapy management services represents the first time that pharmacists will be eligible to receive payment from Medicare for provid-

ing many patient care services. Under MMA, each drug plan sponsor is required to establish a medication therapy management program with the assistance of a pharmacist and a physician in order to ensure that covered Part D drugs are used appropriately for targeted beneficiaries. Targeted beneficiaries include individuals with multiple chronic conditions, such as asthma, diabetes, hypertension, hyperlipidemia, and congestive heart failure, who are taking multiple medications and are identified as being likely to incur annual drug costs that exceed a level specified by the Secretary of HHS. The legislation explicitly states that the medication therapy management services may be provided by a pharmacist and that the drug plan sponsor must take into account the resources and time required to implement the program when establishing pharmacist fees.

ASHP's top federal legislative priority in recent years has been obtaining the recognition of pharmacists as health care providers under Medicare Part B. It is important to point out that the medication therapy management program is distinct from, but related to, pharmacist provider status recognition. The medication therapy management program is recognition of the value of a type of service, rather than recognition of the health care professionals who most often provide that service. Other health care professionals may also provide medication therapy management under MMA.

Medication therapy management is being recognized as a Part D drug benefit that will be administered by private drug plan sponsors rather than as a component of Part B, which recognizes other provider services. As a result, drug plan sponsors rather than CMS or state practice acts will determine the scope of the covered benefit and payment rates. Pharmacy will need to educate drug plan sponsors that medication therapy management services go far beyond a call

center and should include face-to-face interactions between pharmacists and others on the health care team and the patient.

The medication therapy management benefit is restricted to beneficiaries covered by Medicare Part D. If beneficiaries choose not to enroll in Part D, they will not be covered by the medication therapy management program.

The medication therapy management provision demonstrates that Congress sees value in including these services in the Medicare program and recognizes that pharmacists will provide a substantial share of the services. Pharmacy now faces the challenge of implementing practice models that will facilitate delivery of the services and convincing drug plan sponsors to establish programs that fully utilize pharmacists' expertise and adequately compensate them.

It will be important for pharmacy to shape medication therapy management programs by educating drug plan sponsors and CMS about care models that are currently in place, such as the Asheville Project in North Carolina, several state Medicaid programs that provide for pharmacist-run medication therapy management services, and the clinical pharmacy services that have become routine in many health systems. ASHP is communicating this information to CMS and has begun to develop tool kits for pharmacists who will work with drug plan sponsors to develop these programs.

The provision of medication therapy management programs is consistent with a marked change in how Medicare views health care. Traditionally, Medicare has paid providers to treat illness, not prevent it. However, provisions in MMA call for improvements in long-term-care management and for more wellness and other preventive measures. MMA recognizes that medication therapy management is a component of

long-term-care management. To ensure that all Medicare beneficiaries have access to medication therapy management regardless of how their medications are covered, the pharmacy community must continue to seek recognition of pharmacists as service providers under Medicare Part B.

### Other MMA provisions

In addition to the discount card and Part D coverage for prescription drugs, Congress included in MMA provisions affecting Medicare's payment policy for providers in a variety of practice settings. Those that affect pharmacy in general and health-system pharmacy in particular include coverage of a limited number of drugs under Part B (outpatient services), changes to payment for durable medical equipment and the drugs used with that equipment, the OPPS, and changes to "best-price" calculations for inpatient purchases by disproportionate-share hospitals that participate in the federal government's 340B program.

Many of these provisions are an attempt to move Medicare, and in the future other government-sponsored payments, to a rate that more closely reflects the actual acquisition cost of medications. For the long term, as the average wholesale price (AWP) is phased out, pharmacy faces a challenge in helping CMS design an adequate reimbursement method that fully covers the cost of the medication and pays for related overhead and pharmacist patient care services.

**Changes to payment for drugs used with durable medical equipment.** Medicare currently pays for durable medical equipment by using a fee schedule based on pricing data that are adjusted each year for inflation. Section 302 of MMA contains language that establishes competitive acquisition programs for such equipment (including items used for infusion and drugs), enteral nutrients, blood products, and transfusion medications. These competitive ac-

quisition programs would be phased in between 2007 and 2009 starting with the 10 largest metropolitan statistical areas, followed by the 80 next-largest areas in 2008 and the remainder in 2009.

Certain products are exempt from a competitive acquisition program, such as inhalation drugs, parenteral nutrition equipment and supplies, and class III medical devices (those that are used to sustain or support life, that are implanted, or that may present unreasonable risk). Items in these exempt categories would continue to be reimbursed under the existing fee schedule established by durable medical equipment regional contractors, with floor and ceiling rates set by CMS and adjusted each year for inflation.

Much of the drug therapy administered through durable medical equipment will not be subject to competitive bidding. However, Congress continues to look for ways to control costs through alternative reimbursement methods or risk sharing through competitive bidding. Most important, providers and patient groups must ensure that access to care is maintained.

**End of the AWP.** Medicare Part B covers certain outpatient prescription drugs and biologicals if they are usually not self-administered and are provided incident to a physician's services. In addition, Part B covers medications necessary for the effective use of covered durable medical equipment, as well as certain self-administered oral cancer and anti-nausea drugs, erythropoietin, immunosuppressives used after organ transplantation, and clotting factors for hemophilia. Vaccines for influenza, pneumonia, and hepatitis B are also covered. The reimbursement method for these drugs is calculated by using the manufacturer-reported AWP.

Throughout the 1990s, the Inspector General of HHS and the General Accounting Office (GAO)

studied actual prices paid by providers and generally concluded that the Medicare program pays more than other purchasers in both the public and private sectors. These studies found that prescribing decisions related to the use of Part B-covered drugs made by physicians in specialty areas were often influenced by the margin retained between the actual acquisition price paid and the amount reimbursed by Medicare on the basis of the AWP. Congress has decided that Medicare should reimburse an amount closer to the marketplace reality. Thus, it is phasing out the AWP for many covered drugs and replacing it with the average sales price (ASP) and, in subsequent years, a competitive acquisition program.

In 2004, some of these drugs covered under Part B will still be reimbursed at 95% of the AWP, including drugs and biologicals furnished before January 1, 2004; blood clotting factors furnished during 2004; drugs and biologicals furnished in 2004 that were not available for Part B payment as of April 1, 2003; pneumococcal, influenza, and hepatitis B vaccines; drugs and biologicals (other than erythropoietin) furnished in connection with renal dialysis therapy; and radiopharmaceuticals and blood products. Other drugs will be reimbursed at 85% of the AWP or the widely available market price as determined by CMS. In 2005 and future years, reimbursement will be based on the manufacturer's ASP plus 6%. Starting in 2006, providers will have the option of choosing between ASP plus 6% or a competitive bidding program.

**Blood clotting factors.** Medicare also pays for blood clotting factors and the items related to their administration for hemophilia patients who are able to use such products to control bleeding without medical supervision. For 2005, CMS is to review a January 2003 report by GAO concerning payment for blood clotting factors and provide a separate pay-

ment schedule for related items and services. The new law states that payment may take into account preparation, special inventory management and storage requirements, ancillary supplies, and patient training. The total amount expended cannot exceed the amount that otherwise would have been spent after accounting for the increase in the medical consumer price index for the 12-month period ending in June of the previous year.

**Services associated with Part B drugs.** Part B covers physician and other health care provider services. Physicians are reimbursed according to a fee schedule that includes three components: physician work, practice expense, and malpractice expense. Under the practice expense component, physicians are reimbursed for certain drug administration services, including services provided by nonphysician personnel. Under the new law, physician reimbursement will be increased for chemotherapy drug administration, therapeutic and diagnostic infusions, and therapeutic, prophylactic, and diagnostic injections. Also, starting in 2005, CMS is directed to use supplemental survey data (that meet certain criteria) in determining reimbursement and promptly evaluate drug administration costs to take into account levels of complexity in administration. CMS is also required to make adjustments to reimbursement of the nonphysician work pool to prevent any reductions because of changes in the AWP payment method. This was accomplished by a waiver of Congress' budget-neutral policy that requires offsetting revenue or reductions to fund the payment increase. In other words, if a physician is receiving an increase in reimbursement for drug administration, it will not be offset by reductions in other services provided by clinical personnel in his or her practice. However, physician specialty groups remain concerned that the increase in prac-

tice costs will not fully offset the reduced payment for drugs.

The new law directs CMS to change its payment policy that covers only the administration of one drug or biological to a patient on a single day by i.v. push injection. Congressional conferees strongly urged CMS to provide payment for multiple push injections in a single day.

In making these changes, Congress was concerned about the impact on the quality of services and patient access to care. Therefore, the legislation requires the Medicare Payment Advisory Commission to review these changes and submit a report to Congress by January 1, 2006, concerning their impact on oncologist services and, the following year, on services provided by other specialists.

There continues to be limited understanding by both Congress and CMS of the impact of these reductions on pharmacists' services. Relatively few policymakers are familiar with pharmacist administration of these medications, particularly in the home care and physician office settings. Because pharmacists' services are not currently covered under Part B, a reduction in what pharmacists are receiving for the products could have a significant impact on patient care.

**Pharmacy supplying fee.** The law provides for a new payment, the "pharmacy supplying fee," for covered immunosuppressive drugs, oral antineoplastic drugs, and oral anti-nausea drugs used as part of a cancer chemotherapy regimen. However, on January 7, 2004, CMS issued an interim final rule regarding payment rates for 2004 that will, in most cases, set them at 85% of the AWP. CMS stated that the pharmacy supplying fee would be bundled into the overall payment because it did not have data indicating that 85% of the AWP is insufficient to cover the cost of supplying these drugs. At the time of writing, the pharmacy community

protested this decision to HHS Secretary Tommy Thompson and key members of Congress. ASHP is seeking information from its members on the potential impact of these reductions on health-system pharmacy practice.

**Changes to the OPPS.** Hospital-based outpatient services are paid for by Medicare according to a prospective payment system by using an ambulatory payment classification (APC) system. For drug therapy there are four payment categories: pass-through, combined (packaged) into the APC, separate drug-only APC, and reasonable-cost basis. Had Congress not acted, reimbursement for most drugs would have been reduced even more than with the change in the law and subsequent revision by CMS. This is because CMS sets payment rates for the OPPS for each calendar year. CMS had published a final rule for 2004 on November 7, 2003. Congress subsequently passed MMA later that month. Health-system pharmacists are most concerned about the reimbursement formula for drugs paid for by a pass-through formula. These are newly approved drugs that are not bundled into an APC and are considered new technology. Because of this designation, the cost can be "passed through" to CMS for no more than two years. After that time, CMS must decide whether to bundle the drug cost into an APC or create a separate APC for just the drug. Drugs paid for on a reasonable-cost basis are, for example, orphan drugs, which CMS has determined, from the nature of their use and their market, should be reimbursed on the basis of a percentage of the AWP ranging from 88% to 94%.

Congress also codified a lower threshold amount (\$50) that would trigger packaging of drugs into an APC. Thus, any drug costing over \$50 would qualify for a separate APC. The rationale was that, at that amount, the cost of the drug was a

significant part of the APC and should be separately reimbursed. On January 6, CMS published an interim final rule that revised its November 7 final rule in light of the enactment of MMA. Reimbursement rates for pass-through drugs for 2004 will be between 88% and 95% of the AWP for single-source drugs, 68% for multisource drugs, and 46% for generics. In 2005, single-source drugs will be reduced to 83% of the AWP.

The provision in MMA requires two important studies for health-system pharmacy, one by GAO and the other by the Medicare Payment Advisory Commission. GAO is required to complete a survey of actual hospital drug acquisition costs in 2004 and 2005 for CMS by April 1, 2005, to determine the reimbursement methodology for 2006 and future years. Once CMS proposes payment rates for 2006, GAO is required to evaluate the proposed rates and submit a report to Congress. The Medicare Payment Advisory Commission is to present a report to CMS by July 1, 2005, on adjusting payment for APCs for outpatient drugs to take into account overhead and related expenses, such as pharmaceutical services and handling costs. Leaders of health-system pharmacy departments and hospital outpatient departments had pointed out that the OPPS did not accurately reflect overhead and related expenses.

**Disproportionate-share hospital inpatient purchases.** Certain disproportionate-share hospitals participate in the Public Health Service's 340B program. 340B refers to that section of the Public Health Service Act that defines 12 categories of publicly funded health care providers. 340B providers are either owned by or under contract with state or local governments to provide health care to a large number of indigent patients.

Under Medicaid, manufacturers pay rebates to state agencies to ensure that the states pay no more than

the best price for a covered outpatient drug. Before the enactment of MMA, inpatient prescription drug purchases by 340B providers were part of the calculation of a manufacturer's best price. The new law modifies the definition of best price to exclude the discounted inpatient drug prices. The provision was effective upon enactment on December 8, 2003. Passage of this provision should enable the extension of outpatient 340B pricing to inpatient purchases by that entity. It remains to be seen whether manufacturers will actually offer 340B pricing for inpatient medications used in disproportionate-share hospitals.

### Hatch–Waxman reforms

Health care spending in the United States continues to soar, with a large portion of that spending dedicated to high-cost prescription medications. When Congress added a new outpatient prescription drug benefit to the Medicare program, it also sought to address some of the factors contributing to these high costs.

Included in MMA are several provisions intended to address the cost of prescription medications, including a provision to speed market entry of generic medications by preventing manufacturers of brand-name drugs from engaging in certain tactics to extend patent life or marketing exclusivity. Congress increased access to generic medications by closing two significant loopholes in the Hatch–Waxman law. The first change prevents entities filing new drug applications from filing for multiple 30-month stays before filing a generic drug application. The second change enables multiple manufacturers of generic products to qualify for a 180-day exclusivity period if they all file their application on their first day of eligibility, thereby creating disincentives for agreements between brand-name and generic manufacturers to keep a generic product off the market.

### Importation from Canada and elsewhere

The price disparity between drugs sold in the United States and abroad continues to grow. As a result, there has been enormous pressure on Congress to make drugs manufactured in FDA-approved facilities available to U.S. citizens by allowing pharmacists, wholesalers, and individual consumers to import medications. MMA includes a provision that addresses this issue, but it essentially maintains the status quo, which makes it illegal for anyone other than a manufacturer to import prescription medications.

The importation provision in MMA, which allows imports from Canada and some 20 other industrialized nations, will become effective if the HHS Secretary certifies that importation would pose no additional risk to the public health and would result in a significant reduction in the cost of covered products to the U.S. consumer. Secretary Thompson and his predecessor, Donna Shalala, have repeatedly declined to make such a certification.

MMA directs the Secretary of HHS to conduct a comprehensive study that identifies current problems with implementing the importation law and a host of associated issues. MMA also directs the Secretary of Commerce to analyze and report on drug pricing practices in other countries and their impact on market access of medications in the United States.

### Discussion

The measures included in MMA really only begin to address the problem of high drug costs. Many have argued that Congress avoided this issue by explicitly blocking the use of Medicare's purchasing power to negotiate prices for lower-cost medications for the elderly and disabled. We can expect the debate to continue.

With the establishment of a Part D benefit for prescription drugs, pol-

icymakers will consider the advantages of moving coverage and reimbursement policy for current Part B drugs into Part D. Pharmacists in hospitals and health systems need to understand the new law and follow the implementing regulations as they are proposed and adopted. ASHP's Web site ([www.ashp.org](http://www.ashp.org)) will carry news and details about these and other provisions as they are implemented. In addition, ASHP's month-

ly Government Affairs Issue Summaries will provide similar coverage.

This article has outlined the provisions in this landmark legislation that affect hospital and health-system pharmacy. Pharmacists should be advocates for their patients as the new law is implemented.

### Conclusion

MMA represents a historic opportunity to make medications and

pharmacists' services more available to Medicare beneficiaries.

### References

1. Medicare Prescription Drug, Modernization, and Improvement Act of 2003, Pub. L. No. 108-173 (2003).
2. Conference Agreement for the Medicare Prescription Drug, Modernization, and Improvement Act of 2003. <http://waysandmeans.house.gov/Special.asp?section=43> (accessed 2003 Nov 22).
3. Iglehart JK. The new Medicare prescription-drug benefit—a pure power play. *N Engl J Med*. 2004; 350:826-33.