

What surgeons should know about...

The new Medicare drug benefit and related reforms: Part I

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Editor's note: On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA), resulting in the largest expansion in the Medicare program's history. Previous articles in the Bulletin have included detailed information on the physician-specific provisions of this legislation, such as its effects on the fee schedule conversion factor and geographic adjustments to physician payments.

This two-part series of articles attempts to answer some of the questions surgeons may have about the new prescription drug benefits, private plan options, and other aspects of this important new law. In Part I, which follows, the authors provide general information about the law's impact on Medicare beneficiaries. Part II, which will be published in next month's Bulletin, will focus more specifically on the act's effects on surgeons and provide a more in-depth overview of certain aspects of the legislation.

What does the MPDIMA do to help Medicare beneficiaries with the costs of their outpatient prescription drugs?

The MPDIMA creates a new Medicare Part D outpatient prescription drug benefit beginning in 2006, which is described below. To help beneficiaries in the interim, the MPDIMA established a discount card and transitional assistance program. Beginning in May 2004, Medicare beneficiaries will be able to sign up for a Medicare-endorsed discount drug card offered by private sector card sponsors. The card will entitle them

to discounts on an array of prescriptions filled by participating retail and mail order pharmacies. The federal government will provide \$600 per year in payments for drugs purchased using their discount cards in 2004 and 2005 to beneficiaries who have incomes of less than 135 percent of the poverty level and no other prescription drug coverage (except Medicare+Choice or Medigap).

What kind of outpatient prescription drug coverage will Medicare beneficiaries have?

The drug benefits available under the new Medicare Part D are limited and have a structure that is different than generally found in prescription drug coverage available to the non-Medicare population. In general, the benefit package offers some front-end coverage, after a deductible, and then no coverage until the catastrophic benefit level is reached.

Part D plan sponsors will have some latitude to offer different benefit packages that are of equivalent or greater value. The Part D drug benefits will first become available January 1, 2006. Beneficiaries will be given the opportunity to enroll in a Part D plan beginning in November 2005.

Specifically, the standard drug benefit will have a \$250 annual deductible, and 25 percent coinsurance on the next \$2,000 in drug spending. There will be a coverage gap, known as the "donut hole," until the annual out-of-pocket limit of \$3,600 (\$5,100 in total drug spending) is reached. At that point, an enrollee will pay

only the greater of 5 percent coinsurance or copayments of \$2 for generics or \$5 for brand-name drugs. All of these benefit thresholds apply in 2006; thereafter, they increase each year by the Part D per capita growth rate. Thus, it is estimated that in 2013 the deductible will be \$445, the initial benefit cap will be \$4,000, and the out-of-pocket limit will be \$6,400 (\$9,066 in drug spending).

The MPDIMA provides very generous drug benefits for low-income Part D enrollees, generally those in families with incomes under 135 percent of the poverty level (about \$12,000 for an individual; \$16,000 for a couple in 2003). Although the law provides for several different categories of eligibility as determined by income and assets, in general, qualified low-income enrollees will be exempt from paying premiums and deductibles, and their copayments will not exceed \$2 for generics or \$5 for nonpreferred brands. Qualified beneficiaries also will have no coverage gap and no copayments once drug costs reach the annual out-of-pocket threshold. Individuals with slightly higher incomes (up to 150% of poverty) and slightly more in assets may qualify for reduced premiums and reduced coinsurance.

Who will be eligible for Part D coverage?

All Medicare beneficiaries are eligible for the Part D drug benefit. Because the new benefit is voluntary in a manner similar to Part B, beneficiaries must decide whether to enroll. Current beneficiaries will have the opportunity to enroll between November 15, 2005, and May 15, 2006. Individuals who first become eligible for Medicare after November 15, 2005, will have the same seven-month period in which to make their initial enrollment decision as exists for Part B, with that period beginning three months before they first become eligible for Medicare. Special en-

rollment periods apply in certain circumstances; otherwise, enrollment outside of the allowed enrollment periods will result in the individual paying increased premiums for the drug benefit.

How will the Part D benefits be delivered?

The Part D drug benefits will be made available to beneficiaries through private drug-only insurance policies sold on an individual basis to Medicare beneficiaries—known as prescription drug plans (PDPs). Drug benefits also may be offered through private coordinated health plans (health maintenance organizations, preferred provider organizations, and so on)—so-called Medicare Advantage-Prescription Plans (MA-PDs) if one is offered in the geographic area in which a beneficiary resides. Beneficiaries will be able to choose a PDP or MA-PD plan located in their area each November during an “open enrollment” period. Plan sponsors will need insurance licenses, and although they will bear most of the financial risk, the government will share risk for high-cost enrollees. Beneficiaries who want to continue drug coverage from a former employer will be excluded from enrolling in Part D. However, employers who offer retiree plans that provide equivalent or better drug coverage will be eligible for government subsidies and favorable tax benefits. Finally, in any geographic region having less than two private drug plan options available, the government will contract with a “fallback” plan. Fallback plans (such as a pharmacy benefit management company) will provide drug benefits under arrangements where they are not at financial risk for the costs of covered drugs.

How will Part D beneficiary premiums be set?

The government will pay 74.5 percent of the average benefit costs for those Medicare benefi-

ciaries who are ineligible for the low-income subsidies; the remaining 25.5 percent will be the enrollee's responsibility. This provision applies to the standard Part D drug benefit package or its actuarial equivalent. The Congressional Budget Office projects that in 2006, the average Part D plan premium will be \$35 per month (or \$420 annually); by 2013 the average monthly premium will grow to \$58 (or \$696 annually). However, the actual amount that an enrollee pays will depend on the premium for the plan chosen. As noted above, low-income beneficiaries will qualify for premium subsidies, and generally those individuals who are fully eligible for both Medicaid and Medicare, or who have incomes below 135 percent of the federal poverty standard and limited resources, will be exempt from paying a premium for the standard drug benefit.

What kinds of tools will prescription drug plans be able to use to manage the cost of the new benefits?

Because most of the drug plan sponsors will bear substantial risk for paying claims, they will have a strong financial incentive to seek out discounts from manufacturers and pharmacies and manage the drug use of their enrollees. The MPDIMA allows drug plan sponsors to use the same types of cost management tools and strategies that are used today in the private market by entities that administer prescription drug benefits for insurers and employer-sponsored health plans. These may include enrollee cost-sharing, such as tiered copayments that favor generic or certain branded drugs over other brand drugs, as well as pharmacy networks, prior authorization, generic substitution, and medication management. However, some constraints are imposed on a plan's cost management measures. For example, while a plan may

require the enrollee to pay a deductible and copayments or coinsurance, it can only do so within certain parameters established within the definition of the standard benefit package or its actuarial equivalent.

The MPDIMA prohibits the government from "interfering" in any drug plan price negotiations or formulary determinations. This provision was controversial during the congressional debate on the legislation and remains so today. Those who advocate allowing the government to negotiate prices believe that in the absence of a government role in negotiations, drug prices will skyrocket, increasing beneficiary out-of-pocket costs and jeopardizing the long-term sustainability of the Part D program. But permitting such a significant expansion of government power in this area seems unlikely at this time. Government price controls applied to pharmaceuticals have consistently failed to muster broad support in Congress.

Can physicians ensure that patients will have access to non-formulary drugs when necessary?

PDPs and MA-PD plans may cover all FDA-approved drugs and biological products (including insulin and vaccines) covered under the Medicaid program. Drugs also may be covered for any medically accepted indication as reflected in compendia recognized by the Secretary of the Department of Health and Human Services. Hence, items covered would include virtually all prescription medications currently on the market except certain types of products excluded from Medicaid, including "lifestyle," fertility, barbiturate, weight-loss, and other drugs. However, plan formularies are only required to cover two drugs in each class and category of drugs. Thus, not all drugs in a particular class may be included in a plan formulary. Moreover, plans

may also design their cost-sharing policies to favor generic products and specific brand-name drugs, requiring the enrollee to pay more out-of-pocket for nonpreferred brand drugs.

Beneficiaries, not physicians, may appeal either the exclusion of a drug from a formulary (noncovered drugs) or to have a nonpreferred brand drug treated as a preferred drug for purposes of the beneficiary copayment. In the case of noncovered drugs, beneficiaries may appeal only if the prescribing physician determines that all other covered drugs on the formulary would be ineffective or have adverse effects. Similarly, if a beneficiary asks for a nonpreferred drug to be treated as preferred for cost-sharing purposes, the prescribing physician must also determine that the plan's preferred drug would be less effective or would have adverse effects for the individual. Plans must have procedures for appeals, including reconsideration by the plan and opportunities for independent external review of decisions that adversely affect beneficiaries.

Will physicians be required to file prescriptions electronically?

No. Although this option was considered during the debate about the drug benefit, Congress ultimately decided to stop short of mandating electronic prescribing. Instead, the new law requires the establishment of federal standards for electronic prescription programs, and requires anyone who submits prescriptions electronically or who is expected to do so by a hospital or health plan to comply with these standards. The deadline for compliance with these standards is April 1, 2008. The law includes protection under the anti-kickback laws and the Stark physician self-referral law for the provision of non-monetary remuneration (in the form of hardware, software, and information technology and

training services related to electronic prescribing) to physicians by hospitals, group practices, and private drug and health plans. [Q]

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