

## **Medicare Prescription Drug, Improvement, and Modernization Act (MMA) Provisions Addressing Waste, Fraud and Abuse in the Medicare and Medicaid Programs**

The MMA provides for certain fraud and beneficiary protections for individuals enrolling in the Medicare prescription drug benefit that begins in 2006. Under current Medicare Advantage rules, prescription drug plan sponsors will be subject to inspections, evaluations, and audits of services, finances, and facilities. In addition, prescription drug plan sponsors must provide written notice to enrollees in advance of a contract termination and disclose certain information required by the Secretary of Health and Human Services relating to financial transactions between parties in interest including, for example, directors, officers, partners and part owners and their spouses, children or parents. (Section 1860D-12(b)(3)(C))

The MMA authorizes the Secretary of Health and Human Service to impose certain intermediate sanctions on prescription drug plan sponsors. The following actions on the part of a prescription drug plan sponsor may lead to civil money penalties, suspension of payments, and any other remedies authorized by law (Section 1860(b)(3)(E)):

- Fails to provide medically necessary items and services required for an enrolled beneficiary;
- Imposes excessive premiums on a beneficiary;
- Expels or refuses to re-enroll a beneficiary;
- Engages in any practice having the effect of denying or discouraging enrollment by an eligible beneficiary;
- Falsifies information furnished to the Secretary; or
- Employs or contracts with any individual or entity that is excluded from participating in Medicare.

The MMA grants the Secretary of Health and Human Services authority to provide appropriate oversight of Medicare-approved drug discount sponsors to ensure compliance with program rules. The Secretary has the right to audit and inspect any of the sponsor's books or records that pertain to the Medicare-approved drug discount card program. If the sponsor or the program no longer meets the applicable requirements or the sponsor has engaged in false or misleading marketing practices, then the Secretary may implement intermediate sanctions or may revoke the Medicare endorsement. (Section 1860D-31(i))

The MMA requires the Federal Trade Commission to study payment for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers. The study will assess any cost differential between prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers and prescription drugs dispensed by mail-order pharmacies not owned by pharmacy benefit managers and community pharmacies. The report to Congress will include information on whether the group health plans are acting in a manner that maximizes competition and results in lower prescription drug prices for health plan enrollees. The findings will help to inform future policy-making as Medicare begins offering a prescription drug benefit. (Section 110)

Under competitive bidding programs required by the MMA, the dynamics of the marketplace will provide incentives for suppliers to deliver items and services in an efficient manner. These changes will not only lower costs but should also help reduce Medicare fraud and abuse by screening out suppliers who do not operate with ethical business practices. The Congressional Budget Office estimates that competitive bidding combined with payment freezes for durable medical equipment saves \$6.8 billion for the Medicare program over 10 years. (Sections 302 and 303)

In a report to Congress mandated by the MMA, the Inspector General will determine the extent to which suppliers of durable medical equipment that are subject to competitive acquisition are soliciting physicians to prescribe certain brands or modes of delivery based on profitability. (Section 302)

The MMA requires the Secretary of Health and Human Services to establish and implement quality standards that independent accreditation organizations will apply to durable medical equipment (DME), prosthetic devices, prosthetics, orthotics, parenteral and enteral nutrition and other items. The quality standards will include consumer service standards. According to the Office of Inspector General, DME fraud is a major and increasingly serious problem that costs taxpayers billions in lost and wasted dollars and deprives vulnerable beneficiaries of the care and support they need. (Section 302)

The MMA eliminates the various abuses pharmaceutical manufacturers had been using to delay consumers' access to low-cost generic drugs. Under the provision amending the Hatch-Waxman law, brand name companies have one 30-month stay on the approval of a therapeutically equivalent generic drug, while generic drug companies that fail to bring a newly approved generic drug to the market within a specified timeframe will forfeit their 180-day market exclusivity. As a result, consumers will save billions of dollars in drug costs, making these medicines more affordable for the elderly, low-income, and uninsured. (Title XI)

Prior to the enactment of MMA, the Medicare program did not cover outpatient prescription drugs except for a limited number administered in physicians' offices, cancer drugs for example, or as part of a hospital stay. The General Accounting Office, the Office of Inspector General and others have found that payments for cancer drugs significantly exceeded physicians' acquisition costs for them. In response, the MMA requires drug manufacturers to submit the average sales price for each of their drugs on a quarterly basis starting in 2005. Civil money penalties can be applied to manufacturers who misrepresent the average sales price information. Manufacturers would also be subject to the False Claims Act. (Section 303)

The MMA requires the Secretary of Health and Human Services to conduct a demonstration project to test the use of recovery audit contractors under the Medicare Integrity Program. These contractors will identify underpayments and overpayments under Medicare Part A and Part B. The demonstration will involve at least 2 States with the highest per capita utilization rates of Medicare services, and involve at least 3 contractors. (Section 306)

The MMA requires the Secretary of Health and Human Services to establish a 3-year pilot program for national and state background checks on employees of long-term care facilities or providers. While some states require background checks under state law, these requirements vary by facility, provider and worker type. The program will identify efficient, effective and economical processes for long-term care facilities or providers to conduct background checks on employees with direct access to residents and patients. The facilities and providers participating in the pilot will include nursing homes, home health agencies, providers of hospice care, providers of personal care services, residential long-term care providers, and intermediate care facilities for the mentally retarded. (Section 307)

The MMA requires public hospitals, not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement will be subject to a civil monetary penalty. The provision applies to hospitals as of July 1, 2004. (Section 947)

The MMA directs \$3 billion additional dollars over the next ten years to the Medicaid Disproportionate Share Hospital (DSH) program, which will help bolster the safety net and increase access to health care. Medicaid DSH payments help to account for the unpaid debt hospitals incur providing uncompensated or poorly compensated care. To ensure that the funding benefits hospitals that serve a disproportionate share of low-income and Medicaid patients, the MMA requires states to submit to the Secretary of Health and Human Services a detailed annual report and an independent certified audit of their DSH payments. (Section 1001)

*Source: U.S. Senate Committee on Finance  
Chaired by Senator Chuck Grassley of Iowa*