

prescription drug benefit faster and more efficient.

#### *G. Anticipated Effects on National Retail Prescription Drug Spending*

Total national retail spending (spending for the total population, not just Medicare beneficiaries) on prescription drugs is projected to be \$153.5 billion in 2004 (last nine months), \$228.6 billion in 2005, and \$95.3 billion in 2006 (first four-and-one-half months). (<http://www.cms.hhs.gov/statistics/nhe/projections-2002/t11.asp>).

In the last nine months of 2004, the total economic impact of savings from discount card activities under the Medicare prescription drug discount card program is estimated to range from \$1.4 billion to \$1.8 billion, representing 0.88 percent to 1.18 percent of total national aggregate retail prescription drug expenditures during that period. In 2005, the total impact is estimated to range from \$2.0 billion to \$2.7 billion, or 0.89 percent to 1.18 percent of total national aggregate retail expenditures for prescription drugs. In the first four-and-one-half months of 2006, we estimate the total impact to range from \$0.4 to \$0.6 billion, or 0.44 percent to 0.59 percent of total national aggregate retail drug expenditures during that period. Thus, the economic impact is estimated to be at most 1.18 percent of total retail prescription drug spending.

One of the factors underlying these estimates of economic impact is our assumptions concerning enrollment in this program. While we believe that our uptake assumptions are reasonable estimates of the likely level of enrollment in this program, we have conducted an additional analysis to provide a sense of how these impact estimates would change if actual program uptake differed somewhat from the assumed levels. In the first 9 months of 2004, if program uptake was anywhere between 15 percent below to 15 percent above the assumed levels, estimated savings from discount card activities would range from \$1.2 billion to \$2.1 billion (assuming capita spending among enrollees remained unchanged), with these savings representing between 0.75 percent to 1.35 percent of national retail prescription drug sales in 2004.

We expect that the various sectors involved in the prescription drug industry will adjust to the impact of this program without significant disruption, just as the industry adjusted to discounts being extended to the privately insured population during the 1990s. The 1990s saw a significant increase in reliance on pharmacy benefit management and the tools commonly

used to manage pharmaceutical benefit costs.

For example, evidence of market adjustment can be seen in the changes in pharmacies' acquisition costs during the 1990s. In the August 2001 HHS Office of Inspector General (OIG) Report entitled "Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products," the OIG reports on changes in pharmacy acquisition costs for both single source and multi-source brand name drugs. The OIG uses the common industry pricing metric of average wholesale price (AWP). The findings from the OIG study indicate that the acquisition prices pharmacies face for a broad spectrum of brand name drugs have been declining as a percentage of AWP during the period 1994 to 1999. Based on 1994 pricing data, the OIG estimates that pharmacies acquired brand name drugs (both single source and multi-source) at a discount of 18.30 percent below AWP. For 1999 pricing data, the OIG estimates a discount of 21.84 below AWP. The OIG reports that this represents an increase of 19.3 percent in the average discount below AWP for which pharmacies were able to purchase a mixture of single source and multi-source brand name drugs. The OIG conducted a similar analysis on the pharmacy acquisition costs related to generic drugs. The OIG March 2002 report "Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products" reported that for generic drugs there was an increase of over 55 percent in the average discount below AWP from 1994 to 1999 at which pharmacies were able to acquire generic drugs (from 42.45 percent below AWP in 1994 to 65.93 percent below AWP in 1999). Thus, during the 1990s, as more customers secured discounts on the purchase of prescription drugs, pharmacies acquired drugs at larger discounts from AWP.

The acquisition costs reported by the OIG are similar to those reported in the PricewaterhouseCoopers (PWC) study conducted for us entitled "A Study of Pharmaceutical Benefit Management," June 2001. That study reported that pharmacies generally now acquire brand name drugs at AWP minus 20 to 25 percent. According to the PWC report, absent a discount arrangement (such as a pharmacy-sponsored senior discount), pharmacies, on average, sell to the uninsured population at full retail price, roughly AWP plus a dispensing fee (generally \$2 to \$3).

We also believe that the Medicare prescription drug discount card program will accelerate the use of generic drugs. The HHS study reports that, generally,

pharmacies earn higher margins on generic drugs. In addition, PWC found that generic manufacturers sometimes provide pricing incentives to pharmacies based on generic volume or market share. These are other examples of adjustments that take place related to the market place in pharmaceuticals.

It is also possible that the requirements of price publication and the establishment of a large number of competing discount cards will lead to greater manufacturer discounts. We expect that access to modern competitive tools will assist in controlling prescription drug costs and improving the quality and efficiency of prescription drug services. We also expect that this program will somewhat level the playing field between the insured and uninsured, and the current differential in pricing between populations with drug coverage and Medicare beneficiaries without drug coverage will be ameliorated.

Further, we do not expect that this program will have any impact on the number of Medicare beneficiaries with drug coverage through employer-sponsored health insurance. Since this program is short-term and it provides \$600 transitional assistance only to a subset of beneficiaries (those with incomes that do not exceed 135 percent of the official poverty line), we do not anticipate that employers will alter their drug coverage in response to this program.

#### *H. Analysis of Effects on Small Entities*

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. If a rule is expected to have a significant economic impact on a substantial number of small entities, the RFA requires that a regulatory flexibility analysis be performed. However, the RFA stipulates that these requirements are applicable to a notice of proposed rulemaking or a rule for which an agency has published a notice of proposed rulemaking. Since Congress specifically authorized us to dispense with a notice of proposed rulemaking, we believe that a regulatory flexibility analysis is not required for this rule. Nevertheless, a regulatory flexibility analysis follows.

The Medicare prescription drug discount card program may involve some impact on a substantial number of small businesses. The current market for delivery of pharmaceutical products, by its nature involves small businesses, similar to other professional health care services such as physician services. The current health insurance market