

Federal budget, but would be a transfer of money due to a decrease in the revenues of entities providing the supply of drugs to consumers. This represents at most 1.18 percent of projected total retail prescription drug spending during the respective periods of 2004 (\$153.5 billion for the last nine months of the year), 2005 (\$228.6 billion), and 2006 (\$95.3 billion for the first four and one-half months of the year), based on the most recent published National Health Expenditures projections (released in February 2003).

In addition to savings from discount card activities, a subset of discount card enrollees—those who qualify for transitional assistance—are projected to save an additional \$2.4 billion in 2004, \$2.6 billion in 2005, and up to \$0.1 billion in 2006 due to the annual \$600 transitional assistance. Beneficiary savings from transitional assistance are funded through the Federal budget, so these savings are a transfer from budget revenue to beneficiaries.

This rule also generates costs and benefits for drug sponsors in the new market created by the Medicare-endorsed drug discount card programs. Net benefits in this new market are generally projected to be positive but small relative to the savings generated for beneficiaries. The net present value benefits range from near zero to approximately \$10 million.

This rule is a major rule as defined in Title 5, United States Code, section 804(2). Accordingly, we have prepared an impact analysis for this rule.

#### *B. Unfunded Mandates Reform Act*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. The UMRA stipulates that this is a requirement before an agency promulgates a notice of proposed rulemaking or promulgates a final rule for which a notice of proposed rulemaking had previously been issued. Since Congress specifically authorized us to dispense with a notice of proposed rulemaking, we believe that the UMRA requirements do not apply to this rule. Regardless, we do not anticipate that this rule would impose costs approaching the \$110 million UMRA threshold.

While this rule does include a data reporting requirement for States, the State costs associated with this activity are expected to be relatively small. As discussed in this document, States will

be required to provide data to CMS that will allow us to identify those beneficiaries who would be ineligible for the Medicare prescription drug discount card program due to the receipt of drug coverage through Medicaid or a section 1115 waiver demonstration. Aggregate State costs associated with this data reporting, including expenses related to data transmissions, quality assurance, and any needed systems changes, are expected to be substantially less than the \$110 million UMRA threshold. Furthermore, as discussed in this document, States will receive Federal reimbursement for a share of these expenditures at the Federal matching rate for administrative expenses under 1903(a)(7).

In terms of territories and tribal governments, this rule imposes no mandatory requirements for these entities, while offering them an additional source of funding that they can elect to take advantage of. As discussed in this document, funds are available for a territory to provide prescription drug assistance to eligible low-income beneficiaries in the territory, if they elect to do so and submit a plan to CMS about how they intend to do it. For tribal governments (specifically pharmacies operated by Indian Tribes and Tribal Organizations, and Urban Indian Organizations (as defined in section 4 of the Indian Health Care Improvement Act)), the rule makes special provisions for these pharmacies to have the opportunity to participate in the networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such pharmacies operate.

In addition, we have determined that this rule would not be an unfunded mandate related to the private sector as defined by the UMRA. In particular, section 101 of the UMRA only requires estimation of direct costs to comply with the definition of a private sector unfunded mandate. While the rule will have an impact on the private sector, we do not expect that this will require direct costs or outlays approaching UMRA's \$110 million threshold.

#### *C. Federalism*

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As noted earlier in this document, a State may choose, on a voluntary basis, to partner with private drug card sponsors to coordinate its State

Pharmacy Assistance Program with the Medicare prescription drug discount card program. States also have the option of paying for some or all of the enrollment fee for some or all non-transitional assistance eligible beneficiaries and the option of paying for some or all of the beneficiary coinsurance liability for some or all transitional assistance enrollees in a State. In addition, some States may decide to educate beneficiaries, particularly dual eligibles who would qualify for transitional assistance (that is, QMBs, SLMBs, & QIs without Medicaid drug coverage) and beneficiaries in State Pharmacy Assistance Programs, about benefits available through the Medicare prescription drug discount card program. All of these are voluntary opportunities for States, and have no Federalism implications. In addition, States with State Pharmacy Assistance Programs may realize savings related to the Medicare prescription drug discount card program to the extent that they provide for coordination of their program with the new Medicare program.

We have also determined that this rule would not impose substantial direct requirement costs on State and local governments. As discussed above, States would likely incur some costs related to data submission activities, but these costs are expected to be small and substantially less than the \$110 million UMRA threshold. Furthermore, CMS has taken a number of steps to minimize the costs related to this program for States. CMS has consulted with State Medicaid Directors on the data submissions process and what mechanisms would be least burdensome and costly to States. In addition, CMS has already held and plans to hold additional information sessions for State officials to help them anticipate and prepare for implementation of this program. Further, we are taking measures to ensure that States are provided with training materials and beneficiary resources so that States can have ready access to materials that they can use if they receive questions from beneficiaries about the program.

#### *D. Limitations of Our Analyses*

The following analyses present projected effects of this rule on Medicare beneficiaries, the Medicare program, total national retail prescription drug spending, small entities, and endorsed sponsors. This section discusses limitations of the analyses conducted in especially sections E and I of this regulatory impact analysis.