

under the Outpatient Prospective Payment System.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We have determined that this proposed rule will have no consequential effect on State, local, or tribal governments.

We have examined this final rule in accordance with Executive Order 13132 and have determined that this regulation would not have any significant impact on the rights, roles, or responsibilities of State, local, or tribal governments.

#### *A. Anticipated Effects*

We have prepared the following analysis, related to the assessment requirements. It explains the rationale for, and purposes of, the rule, details the costs and benefits of the rule, analyzes alternatives, and presents the measures we are using to minimize the burden on small entities. As indicated elsewhere, we are making changes to payments for drugs and related services in response to the requirements of section 429(b) of BIPA and section 1842(o) of the Act. It is our intent to revise our drug payment system and pay appropriately for the administrative costs related to furnishing drugs. We provide information for each of the policy changes in the relevant sections in this rule. The provisions of this rule are changing only our payment rates for drugs and related services. This rule does not impose reporting, record keeping, and other compliance requirements except as described in section II.A.2.b New Drugs and Drugs with Patent Expirations and section II.A.4.b Average Sales Price. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule.

#### *B. Impact of Approaches to Revising the Current Payment System*

The proposed approach of basing our reform efforts on the comparability provision (Option 1) in the statute and issuing additional guidance to our contractors would result in decreases in Medicare expenditures for drugs of \$4.1 billion over the ten-year period FY 2004 through 2013. The effect of implementing an average list AWP discount (Option 2) is dependent on the level of the discount. We are seeking comment on the appropriate discount in the range of 10 percent to 20 percent. At 10 percent, the impact of this proposal

is \$5.1 billion for FY 2004 through 2013. At 20 percent the impact is \$14.3 billion for FY 2004 through 2013. The implementation of market monitoring (Option 3) is also dependent on the list AWP discount since the discount impacts the drugs that have not been studied by the OIG and GAO. At a 10 percent discount for the drugs that have not been studied, the impact of this proposal is \$16.1 billion for FY 2004 through 2013. At 20 percent, the impact is \$19.4 billion for FY 2004 through 2013. The proposed approach of basing our reform efforts on the establishment of a competitive acquisition program and Average Sales Price system (Option 4) is dependent on the ASP markup. At a 1 percent markup the impact of this proposal for FY 2004 through 2013 is \$13.5 billion excluding DME drugs and \$27.6 billion including DME drugs. At a 12 percent markup the impact of this proposal for FY 2004 through 2013 is \$7.6 billion excluding DME drugs and \$21.2 billion including DME drugs.

#### *C. Impact on Payments Related to Furnishing or Administering Drugs*

We have simulated the impact of our proposed increase in payments for the costs of furnishing or administering drugs. Medicare payments for physician fee schedule services are estimated to increase by \$1.6 billion over the ten-year period FY 2004 through 2013. For ESRD facility costs related to furnishing separately billable ESRD drugs, we would set payments budget neutral to the reductions in drug payments. For DME inhalation, DME home infusion, and oral drugs provided by pharmacies, we are seeking comment on the appropriateness of any changes to the payments for the administrative costs of furnishing these drugs.

#### *D. Alternatives Considered*

This proposed rule contains the four alternative approaches to reforming the current payment methodology that we considered, each of which has been discussed in detail. We are seeking comment on these approaches. We expect to select one of these approaches after reviewing all public comments received on the proposed rule and making any necessary modifications.

#### *E. Impact on Beneficiaries*

We have simulated the effect of changes in beneficiary copayments for drugs and related changes in beneficiary Part B premium payments resulting from the implementation of the four options for reforming the AWP system. The proposed approach of basing our reform efforts on the comparability

provision in the statute and issuing additional guidance to our contractors would result in decreases in these payments by beneficiaries of \$2.6 billion over the ten-year period FY 2004 through 2013. The effect on beneficiary payments resulting from the implementation of an average list AWP discount is dependent on the level of the discount. At 10 percent, the proposal will save beneficiaries \$3.2 billion for FY 2004 through 2013. At 20 percent, the proposal will save beneficiaries \$9.1 billion for FY 2004 through 2013. The implementation of market monitoring is also dependent on the list AWP discount since this impacts the drugs that have not been studied by the OIG and GAO. At a 10 percent discount for the drugs that have not been studied, the proposal will save beneficiaries \$10.3 billion for FY 2004 through 2013. At 20 percent, the proposal will save beneficiaries \$12.3 billion for FY 2004 through 2013. The proposed approach of basing our reform efforts on the establishment of a competitive acquisition program and Average Sales Price system is dependent on the ASP markup. At a 1 percent markup the proposal will save beneficiaries \$8.6 billion excluding DME drugs and \$17.6 billion including DME drugs. At a 12 percent markup this proposal will save beneficiaries \$4.8 billion excluding DME drugs and \$13.5 billion including DME drugs.

Beneficiaries will pay an additional \$1.1 billion in copayments and related Part B premium increases as a result of the proposed changes to the Medicare physician fee schedule.

As described in section II.C, we do not believe that any beneficiaries will experience drug access issues as a result of our four proposed options. We intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future if necessary.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this regulation.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2003.

**Thomas A. Scully,**  
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 13, 2003.

**Tommy G. Thompson,**  
Secretary.

**Addendum A**