

1 year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities). We have simulated the effect of the proposed changes to the practice expense RVUs described earlier. The net effect of the changes we are proposing will not materially increase or decrease Medicare expenditures for physicians' services because the statute requires that changes to RVUs cannot increase or decrease expenditures more than \$20 million. Since increases in payments resulting from RVU changes must be offset by decreases in payments for other services, the proposed practice expense changes will result in a redistribution of payments among physician specialties. The RVU changes in this proposed rule have an estimated aggregate redistributive effect of approximately \$190 million dollars. (Tables 11 and 12 which appear later in this section reflect the estimated specialty impacts.) Therefore, we are considering this proposed rule to be a major rule because it is economically significant, and, thus, we have prepared a regulatory impact analysis.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a Regulatory Flexibility Analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives and less significant adverse economic impact on the small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

For purposes of the RFA, physicians, nonphysicians, and suppliers are considered small businesses if they generate revenues of \$6 million or less. Approximately 95 percent of physicians (except mental health specialists) are considered to be small entities. There are about 700,000 physicians, other practitioners and medical suppliers that receive Medicare payment under the

physician fee schedule. The analysis and discussion provided in this section as well as elsewhere in this proposed rule is intended to comply with the RFA requirements.

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 expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This proposed rule would not impose unfunded mandates on State, local, or tribal governments, or on the private sector of more than \$110 million dollars.

We have examined this proposed 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.

We have prepared the following analysis, which together with the rest of this preamble, meets all 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 propose to use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we propose to make changes to the Medicare Economic Index, refine resource-based practice based practice expense RVUs and make a variety of other minor changes to our regulations, payments or payment policy to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. We provide information for each of the proposed policy changes in the relevant sections in this proposed rule. As discussed elsewhere in this proposed rule, the provisions of this proposed rule, if adopted, would only change Medicare payment rates for physician fee schedule services. While this rule would revise the definition of diabetes for the purposes of outpatient diabetes self-management training, it does not impose reporting, record-keeping and other compliance requirements. We are unaware of any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives.

A. Resource-Based Practice Expense Relative Value Units

Under section 1848(c)(2) of the Act, adjustments to RVUs may not cause the amount of expenditures to differ by more than \$20 million from the amount

of expenditures that would have resulted without such adjustments. We are proposing several changes that would result in a change of expenditures that would exceed \$20 million if we made no offsetting adjustments to either the conversion factor or RVUs.

With respect to practice expense, our policy has been to meet the budget neutrality requirements in the statute by incorporating a rescaling adjustment in the practice expense methodology. That is, we estimate the aggregate number of practice expense relative values that will be paid under current and proposed policy in CY 2004. We apply a uniform adjustment factor to make the aggregate number of proposed practice expense relative values equal the number estimated that would be paid under current policy.

Table 11 shows the specialty level impact on payment of changes being proposed for CY 2004. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. The average change in total revenues would be less than the impact displayed here since physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the physician fee schedule. For instance, independent laboratories receive more than 80 percent of their Medicare revenues from clinical laboratory services that are not paid under the physician fee schedules. The table shows only the payment impact on physician fee schedule services.

We modeled the impact of four changes to the practice expense methodology and illustrated the effect in table 11 below. The column labeled "Utilization Data" shows the effect of updating the practice expense methodology to add 2002 utilization data for codes that did not exist in the 1997–2000 period. In general, updating the methodology with the latest utilization data will have the largest impact on payment for a new service where a code was established in 2002. In some cases, the practice expense RVU will increase (for example, 64561—Implant Neuroelectrodes and 52001, Cystoscopy Removal of Clots). In other cases, they will go down (96567—photodynamic treatment skin and G0249—Providing test materials and equipment for home INR Monitoring, 77418—Radiation Treatment Delivery—Intensity Modulated Radiation). For most specialties, new codes represent a