

million or more in any 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 physician fee schedule changes that we are adopting in this final rule. We are making several changes to the physician fee schedule RVUs in this final rule. In general, section 1848(c)(2)(B)(ii)(II) requires that changes to RVUs cannot increase or decrease expenditures more than \$20 million. Thus, changes to the RVUs made pursuant to section 1848(c)(2)(B)(ii)(II) must be budget neutral. That is, increases in payments resulting from RVU changes must be offset by decreases in payments for other services and there will be redistribution in payment among physicians, practitioners and suppliers that bill Medicare for physician fee schedule services. We expect that the changes we are making to the physician fee schedule RVUs under section 1848(c) will result in a redistribution of Medicare allowed charges of more than \$100 million in one year. For this reason, we are considering this final rule to be economically significant. Therefore, this final rule is a major rule and 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 final 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, non-physician practitioners, 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 900,000 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 final rule complies 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 final 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 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.

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 final rule, we are making changes to the Medicare Economic Index, refining resource-based practice based practice expense RVUs, creating new codes for dialysis patient visits to their physicians and making a variety of other 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 policy changes in the relevant sections in this final rule. While this rule revises 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 final rule contain a description of significant alternatives.

A. Physician Fee Schedule Relative Value Units

As indicated above, we are making changes to the work and practice expense RVUs under the provisions of

section 1848(c)(2) of the Act and section 429(b) of BIPA. 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 making several changes under section 1848(c)(2) that would result in a change of expenditures that would exceed \$20 million threshold 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 revised policy in CY 2004. We apply a uniform adjustment factor to make the aggregate number of revised practice expense relative values equal the estimated number that would be paid under current policy. We are applying this policy for all changes that we are making under section 1848(c).

Table 26 shows the specialty level impact on payment of changes being made 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 17 of their revenues from physician schedule services and the remainder for laboratory fee schedule services that are unaffected by this rule. We modeled the impact of all changes to the relative value units and illustrated their effect in table 26. The column labeled "NPRM" shows the combined effect of all of the changes contained in the August 15, 2003 proposed rule (see 68 FR 49033 to 49038 for a detailed discussion of each provision).

The column labeled "Practice Expense Refinements" shows the impact on payment from further changes to the practice expense inputs that we made using information that became available to us since the proposed rule. In some cases, we made changes to the practice expense inputs in response to public comments. In other situations, we may have received