

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million to \$25 million in any 1 year. For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, 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. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the IPPS, we classify these hospitals as urban hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing a final rule that has been preceded by a proposed rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule will not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule in light of Executive Order 13132 and have determined that it will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

The following analysis, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act. The final rule will affect payments to a substantial number of small rural hospitals as well as other classes of hospitals, and the effects on some hospitals may be significant.

II. Objectives

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that

payments are sufficient to adequately compensate hospitals for their legitimate costs. In addition, we share national goals of preserving the Medicare Trust Fund.

We believe the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of this payment system are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

III. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2004, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but we do not attempt to predict behavioral responses to our policy changes, and we do not make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix. In the May 19, 2003 proposed rule, we solicited comments and information about the anticipated effects of the changes on hospitals that we had proposed and our methodology for estimating them. Any comments that we received in response to the proposed rule are addressed in the appropriate sections throughout this final rule.

IV. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs encompass nearly all general short-term, acute care hospitals that participate in the Medicare program. There were 42 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment method for these hospitals. Among other short-term, acute care hospitals, only the 47 such hospitals in Maryland remain excluded from the IPPS under the waiver at section 1814(b)(3) of the Act.

There are approximately 768 critical access hospitals (CAHs). These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. The remaining 20 percent are specialty hospitals that are excluded from the IPPS. These specialty hospitals include psychiatric hospitals and units, rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals. The impacts of our policy changes on these hospitals are discussed below.

Thus, as of April 2003, we have included 4,049 hospitals in our analysis. This represents about 80 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals.

V. Impact on Excluded Hospitals and Hospital Units

As of July 2003, there were 1,086 specialty hospitals excluded from the IPPS that were

paid instead on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. Broken down by specialty, there were 478 psychiatric, 216 rehabilitation, 300 long-term care, 81 children's, and 11 cancer hospitals. In addition, there were 1,405 psychiatric units and 985 rehabilitation units in hospitals otherwise subject to the IPPS. Under § 413.40(a)(2)(i)(A), the rate-of-increase ceiling is not applicable to the 47 specialty hospitals and units in Maryland that are paid in accordance with the waiver at section 1814(b)(3) of the Act.

In the past, hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Hospitals that continue to be paid based on their reasonable costs are subject to TEFRA limits for FY 2004. For these hospitals, the update is the percentage increase in the excluded hospital market basket, 3.4 percent.

Inpatient rehabilitation facilities (IRFs) are paid under a prospective payment system (IRF PPS) for cost reporting periods beginning on or after January 1, 2002. For cost reporting periods beginning during FY 2004, the IRF PPS is based on 100 percent of the adjusted Federal IRF prospective payment amount, updated annually. Therefore, these hospitals are not impacted by this final rule.

Effective for cost reporting periods beginning on or after October 1, 2002, LTCHs are paid under a LTCH PPS, based on the adjusted Federal prospective payment amount, updated annually. LTCHs will receive a blended payment (Federal prospective payment and a reasonable cost-based payment) over a 5-year transition period. However, under the LTCH PPS, a LTCH may also elect to be paid at 100 percent of the Federal prospective rate at the beginning of any of its cost reporting periods during the 5-year transition period. For purposes of the update factor, the portion of the LTCH PPS transition blend payment based on reasonable costs for inpatient operating services would be determined by updating the LTCH's TEFRA limit by the excluded hospital market basket (or 3.4 percent).

The impact on excluded hospitals and hospital units of the update in the rate-of-increase limit depends on the cumulative cost increases experienced by each excluded hospital or unit since its applicable base period. For excluded hospitals and units that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these hospitals and hospital units receive. Conversely, for excluded hospitals and hospital units with per-case cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that will not be reimbursed.

We note that, under § 413.40(d)(3), an excluded hospital or unit whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus 50 percent of the difference between its reasonable costs and 110 percent of the limit, not to exceed 110 percent of its limit. In