

C. Regulatory Flexibility Act

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 \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

In the preamble of the May 9, 2002 proposed rule, we stated that we believed it would be difficult to quantify the impact of the proposed changes and solicited comments on how such an impact estimate could be developed. We did not receive any comments on this point. Neither the proposed EMTALA rule published on June 16, 1988 (53 FR 22513) nor the interim final rule published on June 22, 1994 (50 FR 32086) included a quantitative analysis of the economic impact of the rule. However, in the preamble to each rule, we explained that because the great majority of hospitals do not refuse to treat individuals or transfer patients inappropriately based on their perceived inability to pay, the economic impact of those rules was minimal. Since this rule is only a modification of the previous EMTALA rules, we believe that the impact of this final rule is also minimal. For the reasons explained above, we are confident that the overall effect of this final rule will be to reduce rather than increase the EMTALA compliance burden for hospitals and physicians. For example, the compliance burden for hospitals will be reduced because off-campus provider-based departments that are not dedicated emergency departments will no longer have any EMTALA responsibilities. The burden for physicians should be reduced by the changes that allow them to be on call simultaneously at multiple locations, and to schedule other procedures while they are on call. Because we do not have enough information to precisely predict the dollar amount of the reduced burden, we have not attempted to produce a quantified estimate of the impact of this final rule. However, based on the reduction in burden relative to current regulations, we have determined that this final rule will not have a significant impact on a substantial number of small entities.

D. Effects on Rural Hospitals

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 604 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 payments to hospitals, we classify these hospitals as urban hospitals. As explained above, the compliance burden and cost associated with this final rule is expected to be significantly less than the burden associated with existing regulations. Based on the reduction in burden relative to current regulations, we have determined that this final rule will not have a significant impact on the operations of small rural hospitals.

E. Unfunded Mandates

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 1 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 that may result in an expenditure, in any 1 year for State, local, or tribal governments or for the private sector of \$110 million.

F. Federalism

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 significant impact on the rights, roles, and responsibilities of State, local, or tribal governments.

G. Executive Order 12866

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

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in this preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ A. Part 413 is amended as follows:

■ 1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

■ 2. Section 413.65 is amended by adding introductory text under paragraph (g) and revising paragraph (g)(1) to read as follows:

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

* * * * *

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of § 489.20(l), (m), (q), and (r) and § 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

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