

1866(a)(1)(M) of the Act. In addition, providers (as identified at § 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or authorized representative, applicable CMS notices in advance of the termination of Medicare services,

including the notices required under § 422.624 of this part.

The information collection requirements associated with § 489.27 are currently approved under OMB PRA approval number 0938-0692.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 422.564, 422.620, 422.624, and 422.626. The new hours associated with these collections are summarized in the chart below.

Section No.	Entity	Estimated Burden Hours
422.620	Hospitals	900-1800
422.624	SNFs/HHAs/CORFs	200,320
422.626 (a) and (c)	M+C Enrollees	4,200
422.626 (e)	M+C organizations	12,600-18,600
422.626 (f)	M+C organizations	600

These requirements are not effective until they have been approved by OMB. If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Office of Regulations Development and Issuances, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850. Attn: Julie Brown, CMS-4024-FC.

And, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VII. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule under the criteria of Executive Order 12866 (September 1993, Regulatory Planning and Review), section 1102(b) of the Social Security Act, the Regulatory Flexibility Act (RFA), Pub. L. No. 96-354, the Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). We estimate a burden of not more than \$10 million associated with this final rule. Thus, this rule does not meet the \$100

million threshold and is not, therefore, a major rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The RFA requires agencies, in issuing certain rules, 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, SNFs, and HHAs are small entities, either by nonprofit status or by having revenues of \$25 million or less annually. For purposes of the RFA, all providers affected by this regulation 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 a 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 of a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. While it will have an impact on small entities, the economic impact on any particular entity will be negligible.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure

in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule would not have such an effect on State, local, or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that would impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This rule does not have a substantial effect on State and local governments.

Although a regulatory impact analysis is not mandatory for this final rule, we believe it is appropriate to discuss the possible impacts of the new appeals procedures on beneficiaries, providers, and M+C organizations, regardless of the monetary threshold of that impact. Therefore, a discussion of the anticipated impact of this rule is presented below.

B. Scope of the Proposed Changes

As discussed in detail above, this final rule establishes new notice and appeal procedures for enrollees when an M+C organization decides to terminate coverage of services by SNFs, HHAs, and CORFs. This rule specifies the responsibilities of M+C organizations and providers in issuing termination notices associated with these new appeal rights. It also clarifies the responsibilities of hospitals and M+C organizations for informing Medicare beneficiaries of their right to appeal a hospital discharge and amends the associated Medicare provider agreement regulations with regard to beneficiary notification requirements. Finally, it revises the existing regulations with respect to M+C grievance procedures. In general, we believe that these changes would enhance the rights of M+C enrollees and other Medicare beneficiaries, without imposing any