

would furnish, and meets one of the medical conditions specified in proposed § 412.23(b)(2)(iii). In addition, as discussed in section II.A, we plan to instruct the FIs in the use of a presumptive eligibility test for verifying compliance with proposed § 412.23(b)(2)(i) that includes only Medicare cases determined to be "reasonable and necessary."

#### G. Conclusion

We believe that the changes we are proposing to § 412.23(b)(2) will help ensure the following:

- The incentives are appropriate for IRFs to admit patients that need and would benefit the most from intensive inpatient rehabilitation.
- The preservation of access to intensive inpatient rehabilitation services.
- IRFs provide distinct services and continue to be compensated with payment rates appropriate for their type of facility.
- The most prudent use of Medicare funds.
- More consistent implementation and enforcement by specifying more clearly what conditions are included in proposed § 412.23(b)(2).

### III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

### IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

### V. Regulatory Impact Analysis

#### A. Introduction

In this proposed rule, we are proposing changes to the 75 percent rule for IRFs. Specifically, we are proposing that 65 percent of all patients treated in an IRF meet one of the proposed specified conditions, as discussed earlier in this preamble. We are also proposing to count comorbidities under certain conditions, as specified in this

preamble, towards meeting the proposed 65 percent rule.

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA), (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

#### B. Executive Order 12866

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).

In this proposed rule, we are proposing changes to the 75 percent rule as described above. We estimate the savings to the Medicare program would be greater than \$100 million. Therefore, this proposed rule would be considered a major rule.

#### C. Regulatory Flexibility Act (RFA) and Impact on Small Hospitals

The RFA requires agencies to analyze the economic impact of our regulations on small entities. If we determine that the regulation will impose a significant burden on a substantial number of small entities, we must examine options for reducing the burden. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals are considered small entities, either by nonprofit status or by having receipts of \$6 million to \$29 million in any 1 year. (For details, see the Small Business Administration's regulation, at 65 FR 69432, that set forth size standards for health care industries.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs. Therefore, we assume that all IRFs are considered small entities for the purpose of the analysis that follows. Medicare fiscal intermediaries and carriers are not considered to be small entities. Individuals and States are not included in the definition of a small entity. Accordingly, we have determined that this proposed rule would have a significant impact on a substantial number of small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that will 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 (MSA) and has fewer than 100 beds. This proposed rule would have a significant impact on the operations of small rural hospitals.

#### D. Unfunded Mandates Reform Act

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 an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of at least \$110 million. This proposed rule would not have a substantial effect on the governments mentioned, or on private sector costs.

#### E. Executive Order 13132

We examined this proposed rule in accordance with Executive Order 13132 and determined that it would not have a substantial impact on the rights, roles, or responsibilities of State, local, or tribal governments.

#### F. Overall Impact

For the reasons stated above, we have prepared an analysis under the RFA and section 1102(b) of the Act because we have determined that this proposed rule is a major rule and the proposed policies set forth in this proposed rule would have a significant impact on all IRFs (small entities and small rural hospitals).

#### G. Anticipated Effects of the Proposed Rule

One of the primary purposes of the regulatory impact analysis is to understand the effects policies would have on facilities. As we analyze the impacts of our proposed policies, we assess the extent to which these policies may unduly harm facilities. If there is evidence that we are unduly harming facilities, we make attempts to mitigate these effects, while ensuring that the proposed policies are fair and achieve the intended policy objectives. The intent of the policy objective of proposed § 412.23(b)(2) and of other policy criteria for IRFs is to ensure the distinctiveness of facilities providing intensive rehabilitative services in an inpatient setting. The distinctiveness of these facilities is what justifies paying them under a separate payment system