

few months and the potential for other hospitals to begin to aggressively increase their charges, and consequently their outlier payments, it is possible this type of aggressive gaming of the outlier policy has become more widespread in recent months.

Because of the extreme uncertainty regarding the effects of aggressive hospital charging practices on FY 2003 outlier payments to date, we are proposing no change to the FY 2003 fixed-loss threshold at this time. The threshold would remain at \$33,560. However, we note that data for the first quarter of FY 2003 inpatient claims will be available soon, and these data may allow us to evaluate the current threshold and whether outlier payments to date appear to be approximately 5.1 percent of the total DRG payments.

### III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As discussed below, we are soliciting comment on the recordkeeping requirements, as referenced in the proposed amendments to § 412.84 discussed in this proposed rule. Under the proposed amendments to § 412.84(h), a hospital may request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. The burden imposed by this section is the time it takes to write the request. We estimate that 120 hospitals would make this request per year and that it would take each one 8 hours for a total annual burden of 960 hours.

If you comment on these information collection and recordkeeping

requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attn: Reports Clearance Officer, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Julie Brown, CMS-1243-P; 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.

### IV. Impact Analysis

#### A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 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 any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). Therefore, we have prepared the quantitative analysis presented in section IV.G. of this preamble.

#### C. Regulatory Flexibility Analysis

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 based on their 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. As stated above, we are presenting a quantitative analysis at section IV.G. of this preamble.

#### D. Effects on Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule (and subsequent 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.

It is clear that the changes being proposed in this proposed rule would affect both a substantial number of small rural hospitals as well as other classes of hospitals, and that the effects on some hospitals might be significant. Therefore, the discussion in section IV.G. of this preamble, in combination with the rest of this proposed rule, constitutes a combined regulatory impact analysis and regulatory flexibility analysis.

#### 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 any proposed rule (or a final rule, which 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 proposed rule would not result in any unfunded mandates for State, local, or tribal governments or the private sector, as defined by section 202.

#### 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 proposed rule in light of Executive Order 13132 and have