

first interim bill) and should include any high-cost outlier payment determined as of the last day for which the services have been billed.

XII. Monitoring

In the August 30, 2002, final rule (67 FR 56014), we discussed our intent to develop a monitoring system that will assist us in evaluating the LTCH PPS. Specifically, we discussed the monitoring of the various policies that we believe would provide equitable payment for stays that reflect less than the full course of treatment and reduce the incentives for inappropriate admissions, transfers, or premature discharges of patients that are present in a discharge-based prospective payment system. We also stated our intent to collect and interpret data on changes in average lengths of stay under the LTCH PPS for specific LTC-DRGs and the impact of these changes on the Medicare program. We stated that if our data indicate that changes might be warranted, we may revisit these issues and consider proposing revisions to these policies in the future. To this end, we have designed systems features utilizing MedPAR data that will enable CMS and the fiscal intermediary to track beneficiary movement to and from a LTCH and to and from another Medicare provider. The Medicare Payment Advisory Commission (MedPac) has endorsed this monitoring activity and is pursuing an independent research initiative that will evaluate all aspects of LTCHs, including the accuracy of data reporting, provision of equivalent services by other providers, growth in the number of LTCHs, and clinical outcomes.

Also, in the August 30, 2002, final rule (67 FR 56014), we explained that, given that the only unique requirement that distinguishes a LTCH from other inpatient acute care hospitals is an average length of stay of greater than 25 days, we continue to be concerned about the extent to which LTCH services and patients differ from those services and patients treated in other Medicare covered settings (for example, SNFs and IRFs) and how the LTCH PPS will affect the access, quality, and costs across the health care continuum. Thus, we will monitor trends in the supply and utilization of LTCHs and Medicare's costs in LTCHs relative to other Medicare providers. For example, we may conduct medical record reviews of Medicare patients to monitor changes in service use (for example, ventilator use) over a LTCH episode of care and to assess patterns in the average length of stay at the facility level. We will consider future changes to LTCH

coverage and payment policy based upon the results of such analyses.

XIII. 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.

XIV. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this final 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 Act), the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4), and Executive Order 13132.

1. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely assigns responsibility of duties) 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 one year). We have determined that this final rule will not be a major rule within the meaning of Executive Order 12866 because the redistributive effects do not constitute a shift of \$100 million in any one year. As we discuss in further detail below, and in section VII.B.1.b. of this preamble, the change to the LTCH PPS rate update cycle will be budget neutral. Therefore, we estimate that there will be no budgetary impact for the Medicare program as a result of the change to the LTCH PPS rate update cycle. Based on the best available data for 194 LTCHs, we estimate that the 2.2 percent increase in the standard Federal rate for the 2004 LTCH PPS rate year will result in an increase in payments of \$32.4 million and there are no significant redistributive effects among any groups of hospitals. (Section VII.C.6. of this preamble includes an estimate of Medicare program payments for LTCH services.)

2. Regulatory Flexibility Act (RFA)

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 \$26 million or less in any 1 year. For purposes of the RFA, all hospitals are considered small entities according to the Small Business Administration's latest size standards with total revenues of \$26 million or less in any 1 year (for further information, see 65 FR 69432, November 17, 2000). Medicare fiscal intermediaries are not considered to be small entities. Individuals and States are not included in the definition of a small entity. We certify that this final rule will not have a significant impact on a substantial number of small entities, in accordance with RFA.

3. Impact on Rural Hospitals

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. For a final rule, this analysis must conform to the provisions of section 604 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. As discussed in detail below, the rates and policies set forth in this final rule will not have a substantial impact on the seven rural hospitals for which data were available that have fewer than 100 beds and that are located in rural areas.

4. Unfunded Mandates

Section 202 of the UMRA requires that agencies assess anticipated costs and benefits before issuing any rule 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 or more. This final rule will not mandate any requirements for State, local, or tribal governments, nor would it result in expenditures by the private sector of \$110 million or more in any one year.

5. 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.