

### B. Additional Changes

We are proposing the following additional changes to the OPPS:

- Adjust payment to moderate the effects of decreased median costs for non-pass-through drugs, biologicals, and radiopharmaceuticals.
- Implement a new method for paying for drug administration.
- Create new evaluation and management service codes for outpatient clinic and emergency department encounters.
- Change status indicators for HCPCS codes.
- List midyear and proposed HCPCS codes that are paid under OPPS.
- Allocate a portion of the outlier percentage target amount to CMHCs and create a separate threshold for outlier payments for partial hospitalization services.
- Create methodology and payment rates for separately payable drugs and radiopharmaceuticals for 2004.
- Make several changes in our current payment policy with regard to payment for Q0081, Q0083, Q0084, and Q0085 to facilitate accurate payments for drugs and drug administration.
- Change the status indicator and payment amount for P9010 by assigning it to APC 0957 (Platelet concentrate) with a payment rate of \$37.30.

### XIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, 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 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.

The OPPS provisions set forth in this proposed rule do 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.

### XV. Response to Public Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments concerning the provisions of this proposed rule that we receive by the date and time specified in the **DATES** section of this preamble and respond to those comments in the preamble to that rule.

### XVI. Regulatory Impact Analysis

#### A. General

We have examined the impacts of this 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.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns 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 1 year).

We estimate the effects of the provisions that would be implemented by this proposed rule would result in expenditures exceeding \$100 million in any 1 year. We estimate the total increase (from changes in the proposed rule as well as enrollment, utilization, and case mix changes) in expenditures under the OPPS for CY 2004 compared to CY 2003 to be approximately \$0.457 billion. Therefore, this proposed rule is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

The RFA requires agencies to determine whether a rule would have a significant economic impact on a substantial number of small entities. 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 (*see* 65 FR 69432).

For purposes of the RFA, we have determined that approximately 37

percent of hospitals would be considered small entities according to the Small Business Administration (SBA) size standards. We do not have data available to calculate the percentages of entities in the pharmaceutical preparation manufacturing, biological products, or medical instrument industries that would be considered to be small entities according to the SBA size standards. For the pharmaceutical preparation manufacturing industry (NAICS 325412), the size standard is 750 or fewer employees and \$67.6 billion in annual sales (1997 business census). For biological products (except diagnostic) (NAICS 325414), with \$5.7 billion in annual sales, and medical instruments (NAICS 339112), with \$18.5 billion in annual sales, the standard is 50 or fewer employees (*see* the standards Web site at <http://www.sba.gov/regulations/siccodes/>). 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 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 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 that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds (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 OPPS, we classify these hospitals as urban hospitals. We believe that the changes in this proposed rule would affect both a substantial number of rural hospitals as well as other classes of hospitals and that the effects on some may be significant. Therefore, we conclude that this proposed rule would have a significant impact on a substantial number of small entities.

#### 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 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 proposed rule would not mandate any requirements for State,