

- Recalibrated the relative payment weights of the APCs.
- Updated the conversion factor and the wage index.
- Revised the APC payment amounts to reflect the APC reclassifications, the recalibration of payment weights, and the other required updates and adjustments.
- Ceased transitional pass-through payments for drugs and biologicals and devices that will have been paid under the transitional pass-through methodology for at least 2 years by January 1, 2004.
- Ceased transitional outpatient payments (TOPS payments) for all hospitals paid under OPPTS except for cancer hospitals and children's hospitals.

B. Additional Changes

We made the following additional changes to the OPPTS:

- Adjusted payment to moderate the effects of decreased median costs for non-pass-through drugs, biologicals, and radiopharmaceuticals.
- Changed status indicators for HCPCS codes.
- Listed midyear and proposed HCPCS codes that are paid under OPPTS.
- Allocated a portion of the outlier percentage target amount to CMHCs and created a separate threshold for outlier payments for partial hospitalization services.
- Created methodology and payment rates for separately payable drugs and radiopharmaceuticals for 2004.
- Changed the status indicator and payment amount for P901 by assigning it to APC 0957 (Platelet concentrate) with a payment rate of \$37.30.

C. Major Changes From the Proposed Rule

- We will apply a \$50 threshold in lieu of the proposed \$150 threshold in determining which drugs to pay for separately.
- We will set payment for all except two orphan drugs that meet our criteria for special payment under the OPPTS at 88 percent of their AWP as established in the April 2003 single drug pricer (SDP). Based on widely available market prices for two orphan drugs, we will set the payment for these two orphan drugs at 94 percent of their AWP.
- We will set payment rates for 2004 for blood and blood products at 2003 payment rates.

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 OPPTS provisions set forth in this final 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 **Federal Register** documents, 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 comments in the preamble to that document.

XVI. Regulatory Impact Analysis

A. General

We have examined the impacts 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 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 will be implemented by this final rule will result in expenditures exceeding \$100 million in any 1 year. We estimate the total increase (from changes in the final rule as well as enrollment, utilization, and case mix changes) in expenditures under the OPPTS for CY 2004 compared to CY 2003 to be approximately \$0.607 billion. Therefore, this final 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 will 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 will 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 will 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