

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 OPSS, we classify these hospitals as urban hospitals. We believe that the changes in this final rule will 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 final rule will 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 final rule will not mandate any requirements for State, local, or tribal governments. This final rule will not impose unfunded mandates on the private sector of more than \$110 million dollars.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this final rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have an impact on the rights, roles, and responsibilities of State, local or tribal governments. The impact analysis (see Table 15) shows that payments to governmental hospitals (including State, local, and tribal governmental hospitals) will increase by 4.9 percent under the final rule.

B. Changes in This Final Rule

We are making several changes to the OPSS that are required by the statute. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We are also required under section 1833(t)(9)(A) of the Act to revise, not less often than annually, the wage index and other adjustments. In addition, we must review the clinical integrity of payment groups and weights at least annually. Accordingly, in this final rule, we are updating the conversion factor

and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2004 as we discuss in sections IX and VII, respectively, of this final rule. We are also revising the relative APC payment weights based on claims data from April 1, 2002 through December 31, 2002. Finally, we are removing two devices and eight drugs and biological agents from pass-through payment status. Alternatives to the changes we proposed and why we did not accept them are discussed throughout this final rule. In particular, see section V.B with regard to the expiration of pass-through payment for devices; see section VI.B with regard to the expiration of pass-through payment for drugs and biological agents.

Under this final rule, the change to the conversion factor as provided by statute will increase total OPSS payments by 4.5 percent in 2004. The changes to the wage index and to the APC weights (which incorporate the cessation of pass-through payments for many drugs and devices) will not increase OPSS payments because the OPSS is budget neutral. However, the wage index and APC weight changes will change the distribution of payments within the budget neutral system as shown in Table 15 and described in more detail in this section. The overall 4.5 percent increase does not take into account the expiration of transitional corridor payments or the end of the hold harmless provisions for small rural hospitals.

A. Alternatives Considered

Alternatives to the changes we are making and the reasons that we have chosen the options we have are discussed throughout this final rule. Some of the major issues discussed in this rule and the sections in which they are discussed follow:

| Issue | Pre- amble section |
|--|--------------------------|
| Drug packaging threshold | VI.B.2. |
| Drug administration | VI.B.4. |
| Adjustment of median costs | II.B. |
| Outlier policy | X.A. |
| Device coding | V.C. |
| Payment adjustment for small rural hospitals. | X.B. |
| Payment for orphan drugs, generic drugs and blood. | VI.B. |
| APC changes | II.A and III.C. |

Conclusion

It is clear that the changes in this final rule will affect both a substantial number of rural hospitals as well as other classes of hospitals, and the effects

on some may be significant. Therefore, the discussion below, in combination with the rest of this final rule, constitutes a regulatory impact analysis.

The OPSS rates for CY 2004 will have, overall, a positive effect for every category of hospital. These changes in the OPSS for 2004 will result in an overall 4.5 percent increase in Medicare payments to hospitals, exclusive of outlier and transitional pass-through payments. We also noted that both the overall 4.5 percent increase and the percent changes to individual classes of hospitals depicted in Table 15 are exclusive of any impacts to those hospitals that would result from the expiration of the transitional corridor payments or the end of the hold harmless provision for small rural hospitals. As described in the preamble, budget neutrality adjustments are made to the conversion factor and the relative weights to ensure that the revisions in the wage index, APC groups, and relative weights do not affect aggregate payments. We also note that both the overall 4.5 percent increase and the percent changes to individual classes of hospitals depicted in Table 15 are exclusive of any impacts to those hospitals that would result from the expiration of the transitional corridor payments or the end of the hold harmless provision for small rural hospitals. The impact of the wage and recalibration changes does vary somewhat by hospital group. Estimates of these impacts are displayed on Table 15.

The overall projected increase in payments for urban hospitals is slightly lower (4.3 percent) than the average increase for all hospitals (4.5 percent) while the increase for rural hospitals is slightly greater (4.9 percent) than the average increase. Again, as noted above, these numbers do not include the effect of the expiration of the transitional hold harmless payments to small rural hospitals. The introduction of a new wage index combined with changes to the APC structure will result in small distributional changes for all categories of hospitals. Rural hospitals will gain 0.2 percent from the wage index change and another 0.2 percent as a result of APC changes. Large urban hospitals will lose 0.2 percent from the APC change, whereas “other” urban hospitals show an increase of 0.1 percent from the APC changes. A discussion of the distribution of outlier payments that we project under this final rule can be found under section XV.E below. Table 16 presents the outlier distribution that we expect to see under this final rule.