

local, or tribal governments. This proposed rule would 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 proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that it would not have an impact on the rights, roles, and responsibilities of State, local or tribal governments. The impact analysis (see Table 23) shows that payments to governmental hospitals (including State, local, and tribal governmental hospitals) would increase by 3.9 percent under the proposed rule.

B. Changes in This Proposed Rule

We are proposing several changes to the OPPS 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 proposed rule, we are proposing to update 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 proposed rule. We are also proposing to revise the relative APC payment weights based on claims data from April 1, 2002 through December 31, 2002. Finally, we are proposing to remove two devices and eight drugs and biologicals from pass-through payment status. Alternatives to the changes we are proposing and why we did not accept them are discussed throughout this proposed 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 proposed rule, the change to the conversion factor as provided by statute would increase total OPPS payments by 3.8 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) would not increase OPPS payments because the OPPS is budget neutral. However, the wage index and APC weight changes would change the distribution of payments within the budget neutral system as shown in Table 23 and described in more detail in this section.

Alternatives Considered

Alternatives to the changes we are proposing and the reasons that we are proposing not to make them are discussed throughout this final rule. Below we discuss options we considered when analyzing methodologies to appropriately recognize the costs of former pass-through items. For a more detailed discussion, see section V.B of this proposed rule regarding the expiration of pass-through payment for devices and section VI.B of this proposed rule regarding the expiration of pass-through payment for drugs and biological agents.

Payment for the Administration of Drugs

As discussed in detail in section VI.B of this proposed rule, we considered the following alternatives with regard to payment for administration of packaged and separately paid drugs:

- Continue to pay under the current drug administration codes (Q0081, Q0083, Q0084, and Q0085). This alternative would pay the same amount for administration of packaged or separately paid drugs, although the data show that the costs are considerably more when packaged drugs are administered and considerably less if separately paid drugs are administered.

- Create eight new HCPCS codes (based on the existing Q codes listed above), with one set of codes for packaged drugs and one set for separately paid drugs. Establish an APC for each. This alternative permits more accurate payment for packaged and separately paid drugs than use of the current codes but imposes a significant burden on hospitals to bill correctly.

- Create six new HCPCS codes (based on the existing Q codes with deletion of Q0085). Establish an APC for each. This alternative permits more accurate payment for packaged and separately paid drugs than use of the current codes and imposes slightly less burden on hospital billing than the eight-code alternative.

- Delete Q0085 and revise the definitions of the other Q codes to once per day. Crosswalk each code billed to one of two APCs that would be paid dependent on the drugs billed on the

same date of service. This alternative permits more accurate payment for packaged and separately paid drugs. It also simplifies hospital billing for drug administration. Under this option, however, hospitals would be required to bill for all drugs they administer, whether packaged or separately paid so that the outpatient code editor (OCE) could properly assign the APC that applies in the case. The systems changes required for this alternative are much more substantial than under any of the other alternatives, and we are considering whether we can implement this change before January 2005.

We modeled the second alternative for purposes of budget neutrality and impact analysis. We await comments before determining what alternative we will undertake for the 2004 OPPS.

Payment for Drugs That Are Not Packaged

As a result of marked and erratic fluctuations in median costs for drugs, biologicals, and radiopharmaceutical agents that are paid separately under the OPPS, we explored several options to determine how best to provide accurate payment for CY 2004. One option was to pay based on our 2002 claims data without any adjustment. We were certain that this would not result in accurate payments because of the magnitude of some of the fluctuations in median costs seen in the data.

Another option considered, to create cost bands similar to those used for New Technology APCs, was rejected because unless very narrow bands were created, this option also would result in inaccurate payments.

Finally, we looked at using the same methodology for moderating payment decreases that we used last year, to limit median cost decreases of 15 percent or more to 50 percent of the difference between the median cost and the amount of decrease greater than 15 percent. This option would enable us to moderate the decreased payment amount on an individual drug, biological, or radiopharmaceutical agent level, which is important in light of the great variations in the data; but the 50 percent adjustment level was not adequate for the level of moderation we believed was required for CY 2004.

The adjustment we put forth in this proposed rule is a 75 percent moderation of decreases of 15 percent or more. Thus, for separately payable drugs, biologicals, and radiopharmaceutical agents for which median costs decreased by 15 percent or more, we are proposing to limit the reduction in median costs to 15 percent plus 25 percent of the difference