

the Act, which gives the Secretary broad authority to designate covered OPD services under the OPPS, we have established criteria which distinguish these 11 drugs from other drugs designated as orphan drugs by the FDA under the Orphan Drug Act. Our determination under this authority to provide special payment for a subset of FDA-designated orphan drugs does not affect FDA's classification of drugs under the Orphan Drug Act. Because these 11 drugs have a low volume of patient use, lack other indications, and have no other source of payment, we allow special treatment of them so beneficiaries can continue to have access to them. Because these 11 drugs are used solely to treat an orphan condition that affects a relatively low number of beneficiaries, hospitals receive payment for a low volume of cases by definition, and the cost of the drug is not spread across other uses. We are concerned that if we were to adopt the commenter's recommendation that we qualify all FDA-designated orphan drugs under a particular volume threshold for special payment under the OPPS, we could be expanding this special payment provision, which is meant to target the small number of orphan drugs that are used solely to treat rare diseases, to drugs that are used for other conditions and indications, for which hospitals would also be receiving payment. Therefore, we are not adding a volume threshold to our criteria for identifying orphan drugs that receive special payment under the OPPS in 2004.

7. Vaccines

Outpatient hospital departments administer large amounts of the vaccines for influenza (flu) and pneumococcal pneumonia (PPV), typically by participating in immunization programs. In recent years, the availability and cost of some vaccines (particularly the flu vaccine) have fluctuated considerably. As discussed in the November 1, 2002 final rule (67 FR 66718), we were advised by providers that OPPS payment was insufficient to cover the costs of the flu vaccine and that access of Medicare beneficiaries to flu vaccines might be limited. They cited the timing of updates to OPPS rates as a major concern. They said that our update methodology, which uses 2-year-old claims data to recalibrate payment rates would never be able to take into account yearly fluctuations in the cost of the flu vaccine. We agreed and decided to pay hospitals for influenza and pneumococcal pneumonia vaccines based on a reasonable cost methodology.

As a result of this change, hospitals, home health agencies (HHAs), and hospices were paid at reasonable cost for these vaccines in 2003. We are aware that access concerns continue to exist for these vaccines; therefore, we proposed to continue paying for influenza and pneumococcal pneumonia vaccines under reasonable cost methodology.

We received no comments regarding our payment proposal for vaccines, and finalize our proposal in this rule.

8. Blood and Blood Products

Since the OPPS was first implemented in August 2000, separate payment has been made for blood and blood products in APCs rather than packaging them into payment for the procedures with which they were administered. We proposed to continue to pay separately for blood and blood products.

The list of APCs containing blood and blood products can be found in the November 1, 2002 final rule (67 FR 66750). We note that the APCs for these products are intended to make payment for the costs of the products. Costs for storage and other administrative expenses are packaged into the APCs for the procedures with which the products are used.

As described in the November 1, 2002 final rule (67 FR 66773), we applied a special dampening option to blood and blood products that had significant reductions in payment rates from 2002 to 2003. For 2003, we limited the decrease in payment rates for blood and blood products to approximately 15 percent.

After careful comparison of the 2003 dampened medians with the 2004 medians from our claims data, we determined that establishing payment rates based on the 2004 median costs would, for many blood and blood products, result in payments that are significantly lower than hospital acquisition costs. In order to mitigate any significant payment reductions and to minimize any compromise in access of beneficiaries to these products, we proposed a 10 percent limit to decreases in payment rates for blood and blood products from 2003 to 2004.

We solicited comment on this proposal, especially from hospitals. Specifically, we solicited comments that include verifiable information about the widely available acquisition cost of commonly used blood and blood products.

We received several comments on this proposal, which are summarized below along with our responses.

Comment: Several hospital groups supported the recommendation made by the APC Panel at its August 22, 2003 meeting and urged us to consider freezing 2004 payment rates for blood and blood products at the 2003 levels. A few commenters recommended that CMS use data provided by suppliers of blood and blood products to help set payment rates for 2004. Two commenters stated that major blood organizations are prepared to share the data for verification with CMS. Another commenter recommended that CMS base payments on either reasonable cost or external data.

Response: After carefully reviewing the concerns expressed by commenters and analyzing the further reductions in payment that would result from using our 2002 claims data, even with the 10 percent limit on payment decreases that we proposed, we are convinced that our payments would be considerably lower than what it costs hospitals to acquire blood and blood products. Further, we are mindful of the increasing number of tests required to ensure the safety of the nation's blood supply, which is adding to the cost of processing blood and blood products. Therefore, in order to ensure that our beneficiaries have uninterrupted access to safe blood and blood products, we agree with the recommendation of commenters and the APC Panel that we freeze payments for blood and blood products in 2004 at 2003 payment levels rather than implement our proposal to limit payment decreases to 10 percent. This will enable us to undertake further study of the issues raised by commenters and by presenters at the August APC Panel meeting, without putting beneficiary access to blood and blood products at risk. Therefore, effective for services furnished on or after January 1, 2004, the payment rates for blood and blood products will not change from their 2003 levels.

Comment: One commenter was concerned that while autologous blood and directed donor blood do not have separate CPT codes, hospitals' costs to obtain them are different. Hospitals can only report charges for the autologous blood unit if the patient receives it; otherwise, hospitals must absorb the cost of the autologous donation. The same commenter also suggested that CMS research the issue of whether providing blood to patients with special needs would increase hospital costs. The commenter stated that hospitals do not receive additional payment when conducting national searches to meet special blood needs. Another commenter was concerned that drugs and biologicals were dampened to a