

which were paid for these vaccines under OPPTS in 2002 are being paid at reasonable cost for these vaccines in 2003. We are aware that access concerns continue to exist for these vaccines; therefore, we propose to continue paying for influenza and pneumococcal pneumonia vaccines under reasonable cost methodology.

#### 8. Blood and Blood Products

From the onset of the OPPTS, we have made separate payment for blood and blood products in APCs rather than packaging them into payment for the procedures with which they were administered. As we explained in the April 7, 2000 final rule (65 FR 18449), wide variations in patient requirements convinced us that we should pay for these items separately rather than packaging their costs into the procedural APCs. Moreover, the Secretary's Advisory Council on Blood Safety and Access recommended that blood and blood products be paid separately to ensure that we did not create any incentives that were inconsistent with the promotion of blood safety and access. Therefore, we propose to continue to pay separately for blood and blood products.

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 believe 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 propose to limit the decrease in payment rates for blood and blood products from 2003 to 2004 by approximately 10 percent.

This is different than the amount by which we limited payment decreases last year because when we applied the dampening methodology used for the 2003 OPPTS to blood and blood products, we observed that it did not sufficiently limit payment reductions for the blood and blood products with large decreases in median cost from 2003 to 2004. Therefore, we are proposing for 2004 a variation of the methodology used for the 2003 OPPTS because we believe that

a 10 percent limit in the decrease in payment rates for blood and blood products would better reflect hospital acquisition costs, ensure appropriate reimbursement to hospitals, and enable continued beneficiary access to 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.

We solicit comment on this proposal especially from hospitals. We are especially interested in comments that include verifiable information about the widely available acquisition cost of commonly used blood and blood products.

#### 9. Intravenous Immune Globulin

Following publication of the proposed rule on August 9, 2002, we received comments urging us to reclassify intravenous immune globulin (IVIG) as a blood product. After carefully reviewing these comments with our medical advisors, we decided to make final our proposal to classify immune globulin as a biological, subject to the same payment policy we implemented for other drugs and biologicals. Our reasons were set forth in the November 1, 2002 final rule (67 FR 66774). Since implementation of the 2003 OPPTS update, we have received further comments on this decision. These commenters continue to assert that we should make special payment provisions for IVIG and reclassify IVIG as a blood and blood product. They have expressed particular concern about the potentially negative impact of our payment policy for IVIG on patient access, especially for those individuals who have primary immune deficiency diseases.

We appreciate the concerns regarding our decision to pay for IVIG in accordance with the payment methodology we applied to other drugs and biologicals in the 2003 update of the OPPTS. We have reviewed the claims data that are the basis for the payment rates in this proposed rule, and our analysis reveals that IVIG would be separately payable in 2004. The claims data for IVIG are robust, and the most recent claims data, when compared with claims data used in earlier updates of the OPPTS suggest that hospital costs are consistent and that hospitals are billing accurately for these products. Therefore, we believe that payment for these

products is appropriate using the methodology we propose to implement for other drugs and biologicals. Therefore, we propose to continue to classify IVIG as a biologic. We solicit comments on this proposal.

#### 10. Drug and Device Coding

We propose to require hospitals to report individual codes for all drugs and devices used during the episode, including those that are packaged.

Last year (CY 2003), the pass-through status of many drugs and devices expired. These drugs and devices were packaged, consistent with the fundamental principles of a prospective payment system. By packaging the costs of items and services into the payment for the primary procedure or service with which they are associated, we encourage hospital efficiency and provide hospitals with the ability to manage their resources with maximum flexibility. We believed that an additional advantage of increased packaging would be that hospitals would no longer need to report codes for the individual items and services included in the package. While we continue to support packaging to the greatest extent possible, the loss of coding information on claims creates some obstacles to accurate rate-setting.

The data for 2002 that we are using for CY 2004 rate-setting still have considerable drug and device coding information. However, for the CY 2005 OPPTS update, for which 2003 data would be used, there will be much less information regarding specific drug and device costs. We do not expect to have as much Medicare claims information on which to base certain decisions such as which drugs to remove from packaged status and pay separately.

This concerns us and has led us to consider the need for drug and device coding. Even though payment is not directly related to that information, we believe that reporting the codes may be in hospitals' best interest because it may result in the most accurate payments.

For example, in setting the weights of certain device-related APCs, we discovered that the median costs of those APCs were higher when we used only claims on which the device codes appeared. Similarly, certain drug administration APCs have higher median costs when separate HCPCS for drugs are reported on the claims.

If we are to continue to price drugs and devices using up-to-date median costs from claims data, we need information on the costs of the items, even when packaged. We propose to require the separate coding of individual drugs and device categories,