October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard, C4-26-05
Baltimore, MD 21244-1850

Subject: CMS-1506-P Medicare Program; The Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Notice

Dear Dr. McClellan:

AABB appreciates the opportunity to offer these comments on the proposed APC rates for blood and blood products in the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the revisions to Medicare payment policies under the Hospital Outpatient Prospective Payment System for calendar year 2007, published in the August 22 Federal Register.

AABB (formerly known as the American Association of Blood Banks) is the professional association representing approximately 8,000 individuals and 1,800 institutions – including hospital-based blood banks, laboratories and transfusion services as well as blood and bone marrow collection facilities – involved in blood banking, transfusion medicine and bone marrow and peripheral blood stem cell collection, processing and infusion.

Blood and Blood Products

As we have noted to CMS on a number of occasions in the past few years, payment for blood and blood products present some unique challenges. Briefly, these include:

- There are substantial differences in the market environment and processes for acquiring blood and blood products, which are collected by nonprofit blood centers, as compared with obtaining drugs and other products.
- There is a critical and ongoing need for continued vigilance to maintain the safety of the nation’s blood supply which contributes to the escalation of the costs of
collecting, processing and storing blood. For example, in 2006, the licensure of a West Nile virus screening test, the introduction of new technologies to increase the shelf life of platelet products, and efforts by blood centers and hospitals to move toward implementation of new, enhanced barcode labeling of blood products together added substantially to hospital costs for blood products.

- Blood and blood products are not commodities or typical hospital services and the standard method for calculating costs under the APC system presents unique problems in accurately estimating blood and blood product costs. While CMS has attempted to deal with these differences in part by the use of simulated cost to charge ratios, this has proven to be only a very limited solution to achieving adequate payment for blood and blood products.

All of these factors contribute to the difficulty in setting adequate payment rates for blood and blood products in the hospital outpatient environment.

AABB appreciates that in the past CMS and the Advisory Panel on APC Groups have demonstrated an understanding of the unique aspects of blood reimbursement and have acknowledged the need for flexibility in setting payment rates. In prior years, CMS has implemented “hold harmless” protection to avoid the imposition of unacceptable payment reductions. Although we are disappointed CMS proposes to use the 2005 claims data in calculating the 2007 APC rates for blood without any hold harmless protection, AABB welcomes the fact that CMS will continue its practice of using blood-specific cost to charge ratios for those hospitals that do not have a separate blood and blood product cost center. However, even with these adjustments the proposed 2007 rates for a number of blood APCs will still be grossly inadequate.

The Department of Health and Human Services (HHS) itself will soon publish nationwide data in the 2005 Nationwide Blood Collection and Utilization Survey Report, which provides evidence of the inadequacy of several APC rates. AABB conducted this survey under a contract with HHS to collect data on a number of issues relating to blood supply and utilization, including cost issues. In this nationwide survey, data were collected from approximately 1,600 hospitals. Hospitals provided information regarding the average amount paid by hospitals in 2004 for blood products. For three of the four products surveyed, the prices paid by hospitals in 2004 were greater than the proposed 2007 APC rates for these products. (See chart below for details.) AABB is particularly concerned about the proposed payment for APC 0954, leukocyte-reduced red blood cells (RBCs), which is the highest volume blood product reimbursed under Medicare. In fact, this blood product represents well over 50 percent of the projected units of all forms of blood and blood products, as indicated in Chart 39 of the proposed rule. Implementation of the proposed APC rates will mean that most hospitals will incur a substantial financial loss in providing blood and blood products to Medicare patients.
### APC, HCPC Code and Descriptor

<table>
<thead>
<tr>
<th>APC</th>
<th>HCPC Code and Descriptor</th>
<th>2007 Proposed Medicare APC Rate</th>
<th>Average Hospital Payment in 2004¹</th>
<th>Difference Between 2007 Medicare Payment Rate and 2004 Average Hospital Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0954</td>
<td>P9016, RBC Leukocytes reduced</td>
<td>$176.89</td>
<td>$201.07</td>
<td>- $24.18 (-13.67%)</td>
</tr>
<tr>
<td>9508</td>
<td>P9017, Plasma 1 donor frz w/in 8 hr</td>
<td>$71.87</td>
<td>$56.29</td>
<td>+ $15.58 (+21.68%)</td>
</tr>
<tr>
<td>0957</td>
<td>P9019, Platelets</td>
<td>$60.28</td>
<td>$63.67</td>
<td>- $3.39 (-5.62%)</td>
</tr>
<tr>
<td>9501</td>
<td>P9035, Platelet pheresis leukoreduced</td>
<td>$488.80</td>
<td>$510.05</td>
<td>- $21.25 (-4.35%)</td>
</tr>
</tbody>
</table>


AABB believes it is reasonable to estimate that the average amount hospitals will pay for these products in 2007 will have increased by a minimum of 10 percent. (This rate of inflation is less than the amount the hospital market basket will have increased over this time period.) Thus it is clear that the proposed APC rates will not cover the cost of blood products, particularly the most commonly transfused product, leukoreduced red blood cells. **AABB therefore would recommend that CMS base the APC rate for these products on the 2004 survey data inflated by 10 percent.** The proposed APC rates for these products follow.

<table>
<thead>
<tr>
<th>APC</th>
<th>AABB Recommended APC Rate</th>
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<tbody>
<tr>
<td>0954</td>
<td>$221.18</td>
</tr>
<tr>
<td>9508</td>
<td>$61.91</td>
</tr>
<tr>
<td>0957</td>
<td>$70.03</td>
</tr>
<tr>
<td>9501</td>
<td>$561.05</td>
</tr>
</tbody>
</table>

It should be noted that these rates are extremely conservative; they only reflect the cost of acquiring the blood products and do not include any allowance for the cost incurred by hospitals for overhead, storage, handling and wastage due to shelf life limitations. In addition, this proposal is consistent with recent recommendations by the Advisory Panel on APC Groups that urged CMS to use external data in setting rates for blood and blood products. They recommended the following at the August 2006 meeting:

“The Panel recommends that CMS reconsider its methodology to develop payment rates for blood and blood products to more accurately reflect the true costs of blood and blood products to hospitals, including using external data.”

AABB is committed to working with CMS to provide any support needed to implement our proposal to help ensure that patients have access to the best possible blood products. AABB is now working with HHS on the latest Nationwide Blood Collection and Utilization Survey. We would welcome the opportunity to work with CMS, along with
HHS, in determining how to capture the most useful blood cost data as part of this survey.

APC 0112

For the past several years, AABB has expressed concern about the inadequate payment for certain apheresis procedures and specifically those procedures assigned to APC 0112, Apheresis, Photopheresis and Plasmapheresis. These procedures are very time consuming and involve the use of very costly disposable supplies. We were, therefore, pleased to learn that the 2007 rate is proposed to be increased and appreciate CMS' efforts in this regards. However, while this represents some improvement, AABB believes that the proposed payment rate will still fall far short of covering the costs of providing these important services.

Thank you for the opportunity to offer these comments. If you have any questions or require additional information, please do not hesitate to contact me at 301-215-0514 or Theresa_l@aabb.org.

Sincerely,

Theresa L. Wiegmann, JD
Director, Public Policy