



*Together, we can save a life*

October 10, 2006

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1506-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: Medicare: Hospital Outpatient Prospective Payment System and CY 2007  
Payment Rates; Proposed Rule [71 FR 163, July 25, 2005; Docket # CMS-1506-P];  
Blood and Blood Products**

Dear Sir or Madam:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Centers for Medicare and Medicaid Services' (CMS or agency) proposed rule titled "*Medicare: Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year (CY) 2007 Payment Rates*" (hereafter, referred to as the proposed rule).

The Red Cross is an independent organization that is organized and exists as a nonprofit, tax-exempt, charitable organization pursuant to a charter granted to it by the United States Congress. The Red Cross, through its 35 Blood Services regions, supplies almost half of the nation's blood for transfusion needs. The Red Cross is committed to the safety of donors and patients, and to meet the best interests of the public we serve.

All patients—including Medicare beneficiaries, who represent the largest group of transfusion recipients<sup>1</sup>—need to have access to the safest and most immediately available blood supply possible. The Red Cross appreciates CMS's longstanding acknowledgment of the importance of adequate reimbursement for maintaining an available and safe blood supply, which the agency expressed in the original April 7, 2000, OPPS final rule by stating, "The safety of the nation's blood supply is a major concern of the Department of Health and Human Services, and we want to encourage appropriate testing and follow-up care."<sup>2</sup> CMS again acknowledged "the need to protect beneficiaries' access to a safe blood supply"<sup>3</sup> in the CY 2006 OPPS proposed rule.

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<sup>1</sup> Analysis of National Hospital Discharge Survey 1999 and 2000 data by PAREXEL International Corporation.

<sup>2</sup> 65 *Federal Register* 18449.

<sup>3</sup> 70 *Federal Register* 42741.

We also appreciate CMS's ongoing commitment to addressing the concerns about blood product reimbursement raised by the Red Cross, others in the blood banking industry, and the Advisory Panel on Ambulatory Payment Classification (APC) Groups (The Panel). In previous years, CMS has responded to these concerns by issuing comprehensive OPPS blood billing guidelines (Transmittals 496 and 18, issued in March 2005) and payment adjustments for some or all blood product APCs (a dampening provision in CY 2003, a payment floor in CY 2004, and payment-decrease limits for low-volume products in CY 2005 and 2006 ).

Additionally, the Red Cross is pleased that CMS has proposed to increase the APC payment rates for several blood products in CY 2007. Increases in payment for key blood products are urgently needed in order to maintain adequate beneficiary access to the nation's blood supply. However, the Red Cross is concerned that even with the proposed increases, the APC payment rates included in the CY 2007 OPPS proposed rule still would not cover many hospitals' average acquisition costs for blood and blood products.

Therefore, the Red Cross urges CMS to continue its commitment to ensuring appropriate blood product reimbursement by increasing the simulated median costs by a minimum of additional 12 percent when setting the final 2007 APC payment rates for all blood products. Below, we discuss the factors that contribute to the need for increased reimbursement and explain the rationale for our recommendation.

## **NEED FOR INCREASED REIMBURSEMENT**

The need for increased APC payment rates is driven by the fact that the cost of blood products continues to increase. Over the past several years, the Red Cross's comments to CMS and The Panel consistently have highlighted the growing complexity and the resulting rise in costs of blood banking operations. An increasingly challenging aspect of blood bank operations is the recruitment of new, qualified, younger blood donors to meet hospital demand and replace aging, repeat blood donors. Donor recruitment and retention are becoming significantly more expensive, driving up the expenses associated with making blood available to patients in need. Newer collection technologies, such as cell separators that can collect leukocyte-reduced pheresis platelets or leukocyte-reduced double red blood cells, also help increase the supply of blood, but bring on costs associated with their procurement, process development and validation, and regulatory oversight.

Costly federally mandated requirements and recommendations by the U.S. Food and Drug Administration and its advisory committees also have significant impact on the increasing costs of blood products. The introduction of new technologies and tests, while improving the availability and safety of blood products, also leads to higher complexity and greater costs. Most recently, for example, the licensure of the West Nile Virus test in early 2006 resulted in significant increase in the cost of that test. New safety-enhancing tests, such as a test for Chagas, are also on the horizon.

Hospitals and blood centers cannot absorb these rising costs, and appropriate reimbursement is critical to hospitals' and blood centers' ability to maintain the supply chain for a safe and adequate blood supply.

## **RATIONALE FOR OUR RECOMMENDATION**

The Red Cross provides approximately 45 percent of the nation's blood supply. As CMS noted in the CY 2007 OPSS proposed rule, blood utilization varies significantly depending on the type of blood component. A volume-weighted analysis of Red Cross sales data for all blood products supplied by the Red Cross shows that, on average, the proposed 2007 APC payment rates for blood products would reimburse hospitals for only 88 percent of the prices that they pay to the Red Cross (net of discounts and rebates).

Although OPSS is not intended to pay 100 percent of aggregate hospital costs, it is important to note that the proposed blood product APC payment rates would not cover hospitals' average *acquisition* costs; therefore, in many cases, these rates would not cover *any* of the overhead costs that hospitals incur internally once the blood has been obtained from the blood supplier. These blood-related overhead costs—which are intended to be captured in the blood product APC payment rates—include expenses associated with critical transfusion services activities such as handling, storage, delivery, and inventory management. When such overhead costs are taken into account, the discrepancy between costs incurred by hospitals and reimbursement becomes even more significant.

The Red Cross believes that CMS could reduce this discrepancy and better account for the costs incurred by hospitals by increasing the simulated median costs by an additional 12 percent when setting the final APC payment rates for all blood products in CY 2007. Increasing all blood product simulated medians by at least 12 percent over the currently proposed rates would result in a significant improvement in reimbursement for products whose OPSS claims data clearly understate true acquisition costs, and would help to ensure continued beneficiary access to the nation's blood supply.

A minimum of 12-percent increase over the currently proposed rates would also address the concerns of The Panel, which issued the following recommendation at its 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.<sup>4</sup>

## **SUMMARY OF RECOMMENDATION**

For the reasons described above, we recommend that CMS increase the simulated median costs by a minimum of 12 percent over the currently proposed rates when setting the final CY 2007 APC payment rates for all blood products. We believe that a minimum of 12-

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<sup>4</sup> August 23-24, 2006, *Panel Recommendations*, p. 3, available at: [http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8\\_2006.zip](http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip)

percent increase to the simulated medians would allow hospitals to more fully recover their true acquisition costs and continue to provide beneficiaries with adequate access to blood and blood products.

The Red Cross appreciates this opportunity to provide public comments on the proposed rule. If you have any further questions or require follow-up, please contact Kamenna Lee, Director, Hospital Sales and Marketing, at 202-303-5443 (phone), 202-303-0078 (fax), or leekam@usa.redcross.org (e-mail).

Sincerely,

A handwritten signature in black ink that reads "Kamenna Lee". The signature is written in a cursive, flowing style.

Kamenna Lee  
Director, Hospital Sales and Marketing  
Biomedical Services  
American Red Cross