



Together, we can save a life

**COMMENTS BY
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**ON BEHALF OF
THE AMERICAN RED CROSS
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Groups (The Panel)
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**On the Need for Adequate Reimbursement for
Blood Collection, Testing and Delivery**

Good Day. I am Dr. Peter Page, Senior Medical Officer, speaking on behalf of the American Red Cross (*Red Cross*). I am a physician with board certification in internal medicine, medical oncology, hematology, and blood banking, with experience in a transfusion service at Boston's Beth Israel Hospital (now Beth Israel – Deaconess) and have been on the faculty of Harvard Medical School. As a salaried employee of Red Cross for over 25 years, my responsibilities have included medical, operational and administrative leadership roles at regional blood centers in New England, upstate New York, Utah, and southern California, and more recently at national headquarters in Washington, DC.

Red Cross would like to thank you for this opportunity to speak to the Advisory Panel on Ambulatory Payment Classification Groups (*The Panel*) regarding the need for timely and adequate reimbursement rates for provision of blood products for transfusion to patients in the outpatient setting.

Red Cross urges *The Panel*: (1) to recognize the substantial federally-mandated changes recently implemented in blood supplier operations and (2) to support efforts to change a lagging reimbursement system by recommending increased payment rates for blood products in CY2005.

Red Cross has considerable interest in helping *The Panel* appreciate the changing environment within the blood industry including the many recent recommendations made to the Department of Health and Human Services (HHS) by an advisory committee to increase blood safety and availability. As recently as last month, the HHS' Blood Safety and Availability Committee (BSAC) recommended the development and maintenance of blood inventories nationwide at the 5-7 day level, instead of the

2-3 day level which is currently the norm for many communities. BSAC noted the critical importance of addressing the lagging reimbursement system. Consistent with these recommendations, Red Cross encourages *The Panel* to recommend to the Centers for Medicare and Medicaid Services (CMS) increased payment rates for blood products in CY2005 to support that goal.

Red Cross is a primary provider of blood products and related services to over 3,000 hospitals and other health care providers. The Red Cross, through its 36 Blood Regions, supplies almost half of the nation's blood products for patients transfusion needs. There have been substantial changes in blood operations, driven by the need to: (1) recruit additional new blood donors to meet increasing patients needs as well as to replace deferred donors, (2) retain the ever-smaller pool of long term qualified repeat donors, (3) provide increased education materials to all prospective donors on new donor eligibility criteria, (4) implement new blood donor deferral requirements, (5) perform additional testing for a larger number of infectious diseases transmissible by transfusion (notably West Nile Virus most recently), and (6) supply sophisticated blood products and services on-demand to hospitals. These developments have contributed to the steadily increasing cost of providing blood products to meet patient transfusion needs.

Red Cross urges *The Panel* to modify recommendations generated at the August 2003 meeting

Red Cross urges *The Panel* to continue supporting efforts to change a lagging reimbursement system. Based on Red Cross' price (i.e., the median acquisition cost for hospitals) data shared with CMS, we estimate that reimbursement rates for blood and blood products are paid at approximately 58% of the hospital's acquisition cost on average, which is 27% *lower* than the 85% rate normally referenced by CMS. While more safety-enhancing tests and procedures are performed on blood donations, reimbursement rates have been substantially under-funded, delayed or proposed for further reduction. Red Cross understands that *The Panel* has made four recommendations in August, 2003 to CMS. *The Panel* recommended:

- (1) that CMS freeze payment rates for blood and blood products at 2003 levels
- (2) that the freeze applies to 2004 and 2005 payment levels
- (3) that the American Association of Blood Banks (AABB) and the Red Cross educate hospitals regarding coding and billing for blood products; and
- (4) that blood and blood products be part of this agenda for consideration of the 2005 payment rates.

CMS did accept *The Panel's* recommendation for 2004 payment rates by freezing payment rates for blood products at the 2003 amounts. **Today, Red Cross would like to address "why" *The Panel* should recommend increased payment rates for blood products for CY2005 rather than recommending once again that they be frozen for a second year at 2003 rates.**

Blood suppliers are forced to implement federally-mandated changes in short timeframes

Providers of blood products and services maintain operations that are growing in complexity due to medical advancements, public expectations, and increasing federal recommendations and regulations. By the time a volunteer donor's blood reaches a patient in need of transfusion, it has traveled through an intricate system of safeguards. The main components of this system include: (1) detailed donor screening, (2) determination of donor suitability, (3) multiple assays to detect infectious agents transmissible by transfusion, (4) further manufacture and processing at the blood center, (5) post-donation blood product quarantine or retrieval, (6) inventory management and transportation to the hospital, and (7) re-typing and cross-matching testing for compatibility between donor and recipient (this last element sometimes performed by the hospital transfusion service and sometimes by Red Cross for outpatients).

The blood supply in the U.S. is safer today than it has ever been; however, advances in testing technology, more stringent donor deferral requirements, and recruitment of replacement donors is expensive. Discovery of West Nile Virus (WNV) in the blood supply in CY2002 resulted in a massive and expensive initiative to meet this new challenge. Just last year, Red Cross and other blood suppliers implemented a new Nucleic Acid Test (NAT) under an Investigational New Drug (IND) application to detect WNV in an unprecedented timeframe. In endemic areas of the United States, Red Cross and other blood suppliers further modified operations from pooled sample testing to individual sample testing as an extra safety measure. This costly change to individual sample testing increased labor and reagent costs but permitted the resumption of collection of blood in endemic areas during a time of marginal blood supply adequacy, while optimizing safety to transfusion recipients. Moreover, in collaboration with federal agencies, blood suppliers conducted volunteer withdrawal of thousands of frozen plasma products previously collected in these endemic areas to mitigate the risk of transmission of WNV through plasma transfusion. This expensive withdrawal (with destruction of substantial numbers of units of plasma for transfusion) was a cost not passed on to hospitals at the time, but will need to be recovered in subsequent fee levels, due to the non-profit status of Red Cross and essentially all other providers of blood products.

The cost of Nucleic Acid Testing (NAT) for HIV-1 and HCV (hepatitis C virus) greatly increased when the test material transitioned from the investigational to the commercial (FDA licensed) phase. The cost of NAT under IND is modest due to the federal requirement that the test kit manufacturer can only recover the cost of producing the test kit reagents during that timeframe. After licensure of NAT for HIV-1 and HCV, however, the for-profit vendors of these test kits increased the price to blood suppliers to incorporate a profit margin. Apart from the additional increase in cost for testing labs, Red Cross must also recover costs of collecting test samples for NAT in an extra and special tube, prompt transportation to testing labs under controlled temperature conditions, labor for testing, validation and maintenance of new equipment, quarantine/inventory costs, confirmatory tests for reactive tests, and notification of donors with disqualifying test results. The total cost of NAT for HIV-1/HCV includes the expense of lost revenue from discarded blood units.

Red Cross is committed to providing safe blood to hospitals for optimal patient care and containment of liability for hospitals. Each incremental advance in blood safety contributes to the rising complexity and cost of managing a safe and adequate blood supply; however, these advances in safety create cost savings for hospitals in other areas as well as the overall health care system. Next month, measures to detect bacteria in platelet products will be implemented that are expected to reduce the risk of morbidity and mortality in transfusion recipients. Currently, bacterial infection from platelet transfusion is the highest infectious risk for transfusion recipients. In past years, complications from bacterial infection in already ill patients have undoubtedly increased their: (1) hospital stay, (2) expenses from broad spectrum antibiotic coverage, and (3) other supportive medical care. The ability to detect and prevent bacterial contamination will also allow commencement of resource-intensive scientific studies to evaluate platelets and other time-sensitive blood products to assess extension of their short shelf life. Any expansion of shelf life would aid in meeting demand and improving availability.

Blood Suppliers are challenged to find new donors as required by increased patient needs and increasing requirements for donor deferrals due to the emergence of new pathogens, new routes of exposure, and new variants of known pathogens

The costs of donor recruitment and collection to meet increasing needs and replace deferred or unavailable donors are substantial and increasing, and continue to challenge the blood industry to meet the demand. Every day in the United States, over 38,000 donations are collected, which barely meet the need for patients requiring transfusion. In general, only 30% of blood donors return to make a second blood donation. Many members of the aging U.S. population have been the primary donors dedicated to repeat their efforts to donate. However, with their aging, they are becoming increasingly less eligible and available to donate. Corporate sponsors for blood drives are less willing and able to provide space for blood collection and paid time off for employees to donate. Accordingly, blood suppliers have been sending paid staff further distances to collect smaller number of units of blood. Collections on weekends and holidays are necessary to meet the demand. All of these additional recruitment and collection challenges increase the cost of those needed extra units of blood. Blood suppliers must be able to apply resources and respond to these changes. When donation levels drop, additional resources for staffing, media campaigns, postage and other recruitment efforts are required to appeal to donors in order to provide an adequate blood supply. For example, in the summer of 2003, Red Cross conducted an unprecedented nation-wide "Save A Life" Campaign which aimed to make blood donation a regular part of life.

Although the increased cost of recruiting new blood donors is one factor in potential cost increases, new donor deferral requirements require new investments in donor education and quicker implementation. New deferrals related to Severe Acute Respiratory Syndrome (SARS), Leishmania, smallpox vaccination, and the recent Hepatitis A epidemic in Pennsylvania are just a few examples of new changes that were implemented very quickly that reduced the pool of eligible donors. The Food and Drug Administration (FDA) has required quick implementation of responses to these public health threats sometimes within as little as 30 days of providing notice. Red Cross

concur with these new donor screening requirements and believes this trend will continue. However, training over 7,000 paid Red Cross' staff involved in determining donor suitability, who collect an average of over 700 sites each day, is expensive and time consuming; rapid implementation of new deferrals system-wide is challenging to say the least.

Red Cross has invested in state-of-the-art information technology and automated systems in collection centers to implement procedural improvements to make the blood donation process more efficient for donors and to provide a blood donation environment appealing to sponsors' and blood donors' time constraints. Red Cross understands the time-constraints for donors and their employers and is making changes to accommodate their needs and still try to meet the demand for blood products.

Although blood products have been barcoded for many years, Red Cross and other major blood suppliers have strongly endorsed a new unifying bar code standard for blood products. This is yet another step that should help improve patient safety. One unifying standard should help reduce medical errors that may be occurring in blood transfusion and will provide additional benefits to blood banks, hospitals and patients by lowering the cost of implementation and allow exchange of inventories so that the needs of patients everywhere can be more easily met. Moreover, a unifying bar code standard may help to expedite investigations of unforeseen events. (This is entirely analogous, but more complex, than the initiatives undertaken to improve accuracy in pharmaceutical drug administration to patients.)

Blood demand is increasing and cost increases from federal mandates and industry standards are passed on to hospitals

The need for blood in the U.S. continues to increase. Despite conservation efforts in transfusion practice (generated in part by patients' concerns about safety as well as cost containment initiatives), the growth and aging of the U.S. population has already increased the need for blood products. Medical and surgical procedures requiring more and more sophisticated blood product support are increasing, such as those for cancer patients, those with sickle cell anemia, and others. The need to assure the on-going availability and safety of blood products requires adequate reimbursement in a timely manner.

As with most supply chains, cost increases at any point along the process are passed on to the next purchaser. Though the blood itself is donated free of charge by the donor (although at potential expense to the donor and the donor's employer), blood suppliers continue to incur increased costs to maintain and upgrade their facilities and for donor recruitment, collection, testing, computers, blood storage, and distribution. These increased costs are due to the increasing demands for a reliable and constant inventory of all blood types, as well as for compliance with changing regulatory requirements and industry standards. **Red Cross believes these investments require prompt and adequate reimbursement to hospitals and a change in the methodology for paying for blood products to provide a safe and adequate blood supply.**

Recommendations to CMS

The Red Cross continues to provide assistance to our customers and other hospital providers by providing resources they need to understand the complex coding and billing issues related to blood products. Red Cross has distributed to hospital professionals over 15,000 copies of the Red Cross publication *Comprehensive Guide to Billing and Reimbursement for Blood, Blood Products, and Related Services*. The Red Cross has sponsored over 150 seminars during the last three years in 21 states educating over 2000 hospital professionals.

Red Cross urges *The Panel* to recommend to CMS the need for increased payment rates for blood products through either: (1) the use of blood supplier-provided industry data, (2) a methodology of bill charges adjusted to cost using a blood specific-ratio of cost-to-charges (RCC) (i.e., similar to the methodology used by CMS to pay for brachytherapy) or (3) through a temporary removal of these products from OPPS and concurrent payment for the products on the basis of reasonable cost. Red Cross would like to thank *The Panel* and the Centers for Medicare and Medicaid Services (CMS) for their time and attention to this need. If you have any questions, I would be glad to answer them.