





September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Proposed Rule (CMS-1656-P)

Dear Acting Administrator Slavitt:

The undersigned organizations of the blood community, representing the nation's blood centers, hospital-based blood banks and transfusion services, and transfusion medicine professionals submit these comments in response to the proposed rule related to the hospital outpatient prospective payment system that was published in the *Federal Register* on July 14, 2016.

The collective blood community applauds CMS for soliciting feedback regarding the current set of HCPCS codes for blood and blood products. We believe that this extensive undertaking has the potential to result in a code set that provides patients with increased access to new technologies and new blood products that protect the public's health and improve clinical outcomes. In addition, we believe that a revised code set can achieve more consistent and accurate billing practices for blood products. We urge CMS to convene stakeholders for a public meeting or collaborative workshop prior to establishing or implementing a thoroughly revised code set for blood products.

In general, we encourage CMS to continue making separate payments for blood and blood products rather than including them in bundled payments. Congress and the Department of Health and Human Services (HHS) recognize that access to a safe and effective blood supply is a national public health priority. Nonetheless, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has raised concerns about inadequacies in reimbursement for blood products. As blood centers and hospitals face increasing economic pressures, it is critical that Medicare and other payers establish appropriate payment policies and adequate reimbursement rates for blood products. This will help ensure that patients have access to safe, clinically effective blood products that protect the public's health.

In addition, we urge CMS to provide a mechanism to immediately begin billing for a new blood product or new technology that is not captured by existing P-codes by establishing a "not otherwise classified" code for blood products. The absence of such a code is especially problematic as the blood industry quickly develops new products and technologies in response to public health threats, such as Zika, Babesia and West Nile Virus. Highlighting threats to the sustainability of the nation's blood system, ACBTSA in 2013 recommended that the Department of Health and Human Services take steps "to improve mechanisms to recover actual costs, including costs of new safety measures." We believe that the establishment of a "not otherwise classified" code for blood products is an important step that is consistent with this recommendation.

Finally, we believe that CMS can achieve more consistent billing practices by (1) establishing a new subsection of HCPCS codes under "Laboratory Services" entitled "Blood Products," (2) revising the order of the code set for blood products, (3) making the descriptors more uniform by relying on one term/abbreviation to describe a processing method or other specific element of each blood product; and (4) updating the blood product codes to align with current clinical practice, manufacturers' needs and the introduction of new products. We believe that these general principles are important in achieving a code set that ensures patient access to important blood products and technologies and results in more consistent billing practices.

The blood community welcomes the opportunity to work closely with CMS on a constructive, collaborative effort to thoroughly revise the HCPCS code set for blood products. If you have any questions, please contact Leah Stone, Director, Public Policy and Advocacy, AABB (301-215-6554, lmstone@aabb.org), Christine Zambricki, Chief Executive Officer, America's Blood Centers (202-654-2902, czambricki@americasblood.org) or Liz Marcus, Director, Hospital Sales and Marketing, American Red Cross (202-303-7980, liz.marcus@redcross.org).

Sincerely,

Miriam A. Markowitz Chief Executive Officer AABB Christine S. Zambricki Chief Executive Officer America's Blood Centers

Christine S. Zambricki

J. Chris Hrouda Executive Vice President Biomedical Services American Red Cross