May 18, 2015

CMS HCPCS Workgroup
c/o Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

*Re: CMS HCPCS Public Meeting*
*May 21, 2015*
*Agenda Item #12*

Dear HCPCS Workgroup:

We are writing on behalf of AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross regarding the critical need for new HCPCS codes to cover the pathogen-reduced platelet and plasma products recently approved by the Food and Drug Administration. Together, our organizations represent virtually every blood center in the United States as well as hospital-based blood banks and transfusion services and professionals involved in all aspects of blood collection, processing and transfusion.

The blood banking and transfusion medicine community has long awaited the introduction of pathogen reduction technologies in the United States. Moreover, the Department of Health and Human Services (DHHS) Advisory Committee on Blood and Tissue Safety and Availability has recognized the need for pathogen reduction on several occasions. As early as 2008, the committee recommended that the Department "adopt as a high priority the urgent development of safe and effective pathogen reduction technologies for all blood transfusion products and implementation as they become available."

This new technology offers a significant improvement in blood safety. Pathogen reduced plasma and platelet products recently approved by the Food and Drug Administration reduce the risks from known, emerging and future transfusion-transmitted infections. This protection is especially important in today's increasingly global health care arena, where the blood supply faces emerging threats from expanding epidemics of Chikungunya, Dengue and other emerging infectious diseases.

Moreover, pathogen-reduced platelets address another pressing blood safety concern and a major cause of transfusion-related morbidity and mortality – bacterial contamination. Pathogen reduction reduces risk from a wide spectrum of potentially-deadly bacteria in platelets. In addition, pathogen-reduced platelets substantially decrease risks associated with graft-versus-host disease.

AABB, America's Blood Centers and the American Red Cross are extremely concerned that without new codes to allow for appropriate billing of pathogen-reduced platelets and plasma patients will not have access to these important new products. While the majority of blood products are transfused in the inpatient setting, an increasing amount of blood is provided in outpatient arenas. For example, one of the largest patient populations to receive platelet transfusions is oncology patients, many of whom are transfused in outpatient clinics.

**Therefore, our organizations strongly support the applications being considered during this meeting for three new HCPCS Level II codes for FDA-approved pathogen-reduced platelet and plasma products (#15.084, #15.085 and #15.086).** We believe there is a clear national operating need for new codes for these products, which are clearly distinguishable from other blood components. Existing HCPCS Level II P codes for individual blood products were based on processing methods – such as leukocyte-reduction and irradiation – which are operationally and clinically different from pathogen reduction. There is a clear need for new codes to address this life-saving technology.

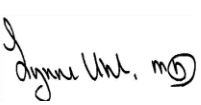
**In addition, on behalf of the blood banking and transfusion medicine community, our organizations request the timely introduction of three temporary HCPCS Q codes to allow hospitals to bill for these new pathogen-reduced platelet and plasma products as soon as they are available.** Because there is no "miscellaneous" code for blood products, hospitals currently would have no means to code and bill for these important new blood products.

Without the ability to bill for and be reimbursed for pathogen-reduced platelet and plasma products, financially-pressed hospitals will be reluctant to purchase and offer them. Moreover, non-profit blood centers, which are already struggling in today's increasingly cost-restrained and competitive environment, lack the means to absorb additional costs associated with these products.

Highlighting threats to the sustainability of the nation's blood system, the Advisory Committee on Blood and Tissue Safety and Availability in 2013 recommended that DHHS take steps to "improve mechanisms to recover actual costs, including costs of new safety measures." Establishing and implementing new HCPCS codes as well as new temporary Q codes for pathogen reduced products are modest steps that will facilitate such cost recovery and patient access to safer blood components.

AABB, America's Blood Centers and the American Red Cross appreciate your prompt action on this important blood safety and patient care issue. If you have any questions or need additional information, please contact Theresa Wiegmann, JD, AABB Director of Public Policy, at 301-215-6554 or theresa_w@aabb.org.

Sincerely,



Lynne Uhl, MD
President
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Louis M. Katz, MD
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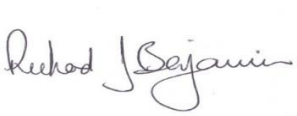

Richard Benjamin, MD, PhD
Chief Medical Officer
American Red Cross

Cc: Chris Ritter