Advancing Transfusion and Cellular Therapies Worldwide

September 2, 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:

AABB is pleased to submit these comments to the Centers for Medicare & Medicaid Services (CMS) 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. These comments focus on CMS' solicitation for feedback regarding the current set of HCPCS P-codes for blood products. AABB submitted separate comments on the proposed payment rates for FY 2017.

AABB is an international, not-for-profit association representing individuals and institutions involved in transfusion medicine, cellular therapies and patient blood management. The association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 1,500 institutions and 7,500 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers.

Executive Summary

AABB commends CMS for reconsidering the HCPCS P-code descriptors for blood products. We believe that this significant undertaking has the potential to achieve two significant goals, including (1) providing patients with increased access to new technologies and new blood products, and (2) achieving more consistent and accurate billing practices for blood products.

We urge CMS to convene stakeholders for a collaborative workshop prior to establishing, finalizing or implementing a thoroughly revised code set for blood products. AABB, whose membership includes experts from hospitals as well as blood centers, would

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welcome the opportunity to work with CMS to address the code set for blood products. The HCPCS codes for blood products are becoming increasingly important. There is clear evidence that outpatient transfusion medicine services are becoming more common, and upwards of 20 percent of transfusions are for the Medicare patient population. The current HCPCS codes for blood products are outdated, confusing and inadequate. We believe that additional discussion, collaboration and time to thoroughly consider current and future HCPCS codes is necessary to achieve the goals of providing increased access to new technologies and new blood products as well as attaining more consistent and accurate billing practices for blood products. Nonetheless, we offer the following general recommendations below:

(1) Retain unique HCPCS codes for each blood product;
(2) Establish a not otherwise classified code for blood products;
(3) Improve the consistency of the descriptors throughout the blood codes, and modify certain existing codes; and
(4) Establish unique HCPCS codes for new blood products that are distinguishable from existing blood products.

1. AABB urges CMS to Continue to Permit Providers to Bill for Blood Products Using Unique HCPCS Codes that Individually Identify Each Product.

AABB encourages CMS to retain unique HCPCS codes for each blood product. We believe that the P-codes should continue to individually identify different blood products based on processing methods since these methods result in blood products that are distinguishable and used for distinctive purposes.

Congress and the Department of Health and Human Services (HHS) recognize that access to a safe and available blood supply is a national public health priority. For well over a decade, HHS' Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has raised concerns about inadequacies in reimbursement for blood products, which can impact patients' access to these life-saving products. As hospitals and blood centers face increasing economic pressures, it is critical that Medicare and other payers ensure patients' access to blood products by establishing appropriate payment policies and adequate reimbursement rates.

Although the majority of blood products are transfused in the inpatient setting, an increasing amount of blood is being provided in the outpatient arena. For example, one of the largest patient populations to receive platelet transfusions is oncology patients, many of whom are transfused in outpatient clinics. 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 blood products. Thus, AABB, believes that hospitals must retain the ability to bill for blood products using unique HCPCS codes and be appropriately reimbursed for individual blood products so that patients have access to safe, clinically effective blood products that protect the public's health.

Importantly, AABB believes that CMS should ensure that its billing system for blood products remains specific with respect to the products provided to patients, since flawed information could impact the availability of medically necessary blood products. Similar to the method that hospitals use to bill for other products covered by Medicare Part B, we urge CMS to retain individual HCPCS codes for unique products with significant therapeutic distinctions. We are concerned that providers would be confused and overly burdened if CMS established a billing protocol for blood products that differs from all other billing methods for clinically distinct items covered under Medicare Part B. Specific HCPCS codes are required to ensure that Medicare beneficiaries have access to clinically effective, cost effective blood products, including specialty blood products, which may be required to achieve optimal health outcomes.

2. AABB Urges CMS to Establish a "Not Otherwise Classified" Code for Blood Products.

AABB urges CMS to establish a "not otherwise classified" code for blood products. Unlike other code series (i.e., J3490 (unclassified drugs), J3590 (unclassified biologics) and J7599 (immunosuppressive drug, NOC) in the J-codes), there is no current mechanism to immediately begin billing for a new blood product or new technology that is not captured by any of the existing P-codes. Significantly, the group of HCPCS codes for blood products is one of the few code sets that does not currently have a "not otherwise classified" code.

This is especially problematic since the blood industry is constantly innovating and bringing new products to market. CMS should encourage such innovation; for example, the blood industry recently developed products in response to emerging threats to the blood supply, such as Zika, Babesia and West Nile Virus. In addition, there are a number of new blood products currently in development (i.e., new pathogen-reduction technologies and freeze-dried plasma). There is a significant delay between the time that FDA approves a product and the time that a new HCPCS code is established. For instance, three pathogen-reduced platelet and plasma products were approved by FDA in December 2014, but specific new HCPCS Level II billing codes were not available until January 1, 2016. As CMS specifies in a document available on its website describing HCPCS Level II coding procedures, "the importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA) even though there is no distinct code that describes the service or item."[1] Consistent with this document, a not otherwise classified blood products code is needed to accommodate important new technologies and new blood products, and to ensure that Medicare beneficiaries have timely access to these lifesaving new blood products.

[1] CMS, "Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures," *available at* https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html (last visited August 12, 2016).

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3. AABB Encourages CMS to Revise the Consistency and Uniformity of the Descriptors Used for Blood Products and to Modify the Descriptors and Codes for Certain Blood Products.

In general, AABB recommends that CMS improve the consistency and uniformity of the short descriptions as well as the long descriptions for blood products. CMS should rely on one term or abbreviation to describe a processing method or other specific element of each blood product. For instance, codes throughout the P-code set use the terms "pher," "pheresis," "pheres," and "aph/pher" to describe apheresis. We recommend that CMS change all of these references to "apheresis," since the terms "pheresis" and "apheresis" are synonyms and inconsistent use of the terms and abbreviations is confusing. Similarly, we urge CMS to consistently list the processing methods and other elements used to identify different blood products in the same order for each code. For instance, the descriptors for codes P9054 (Blood, l/r, froz/degly/wash) and P9057 (Rbc, frz/deg/wsh, l/r, irrad) include similar elements in different orders. As a result, the descriptors are confusing, difficult to decipher and result in inconsistent billing practices.

Additionally, we believe that CMS could achieve more consistent billing practices by changing the order of the products in the code set to ensure that codes involve the same category of blood (i.e., plasma, platelets and red blood cells) are listed in consecutive order. Currently, the categories of blood products are scattered throughout the set of codes, making it challenging for coders to identify the most appropriate code. CMS should consider a numerical system that can accommodate future products in each blood category (for example, assigning red blood cell products to P90XX codes, platelet products to P91XX codes, and plasma products to P92XX codes). CMS may consider establishing a new subsection of the HCPCS code set under "Laboratory Services" entitled "Blood Products." At present, all blood products are contained in a subsection of "Laboratory Services" entitled "Miscellaneous Pathology," which is difficult for coders to locate.

AABB agrees with CMS that several current HCPCS descriptors could benefit from being updated and clarified. We encourage CMS to consider the following modifications to existing descriptors:

- **Codes P9019 (Platelets, each unit), P9031 (Platelets leukocytes reduced), P9032 (Platelets, irradiated) and P9033 (Platelets, leukoreduced irrad):** Modify the descriptors to specify that products are random-donor products.

- **Code P9020 (Platelet rich plasma unit):** Remove this code from the P-codes and add the product as a new Q-code, since this product is an autologous transfusion used for wound care.

- **P9022 (Washed red blood cells unit):** Add leukocyte reduced to the short and long descriptors, since washed red blood cells are also leukocyte-reduced. Currently, no one

code adequately describes the product, which results in coders inconsistently using either P9022 or P9016 (RBC leukocytes reduced).

- **Albumin products (P9041, P9045, P9046 and P9047) and plasma protein fraction product (P9048):** Remove from the P-code series these injectable biologic solutions that are not blood products, and reassign the products to new J-codes.

4. AABB Recommends that CMS Establish Unique HCPCS Codes for Certain New, Clinically Differentiated Blood Products

AABB encourages CMS to establish new HCPCS codes to support appropriate payment policies and reimbursement rates for new blood products that have the ability to improve safety, protect the public's health, reduce adverse events, and improve patients' clinical outcomes. The current code set does not capture several recently approved, clinically differentiated blood products that have significant benefits for patients and the public's health. AABB is concerned that without the ability to bill and be reimbursed for new technologies, including but not limited to the products described below, hospitals that are otherwise facing significant financial pressure will be reluctant to purchase and offer the life-saving new technologies. Thus, CMS should establish unique codes for these products to ensure that Medicare beneficiaries have access to these important products.

A. Bacterially-Tested Platelets

AABB recommends that CMS establish new, separate HCPCS codes for bacterially tested platelet products, which represent an important new safety advancement and are clearly distinguishable from other blood components. Bacterial contamination of platelets has been and continues to be a leading risk of transfusion therapy. Approximately 1 in 2,000 to 3,000 platelet transfusions are contaminated with bacteria, risking serious septic transfusion reactions leading to morbidity and mortality.

New technology recently approved by the Food and Drug Administration (FDA) to test platelets for bacteria closer to the time of transfusion significantly reduces this risk, thus offering patients safer transfusions. In addition to improving the safety of platelet products, this particular bacterial testing allows for extended shelf-life of platelets. Until the product was approved, platelets had to be transfused within five days of collection. When tested with this new technology, the shelf-life can be extended to seven days, which contributes to increased efficiency and minimization of waste of these critical biologics and can help prevent blood shortages.

AABB is concerned that without new codes to allow for appropriate billing of bacterially-tested platelets, patients will not have access to these new products, which offer increased safety and improved clinical outcomes. As mentioned above, HCPCS codes for blood products are based on processing methods. We believe there is a clear operating need for new

codes for these products, since bacterial testing is operationally and clinically different from other processing methods. Thus, bacterially tested platelet products are distinguishable from other blood components, and there is a clear need for new codes to address this potentially life-saving technology.

B. Apheresis Platelets Stored in Platelet Additive Solution

AABB urges CMS to establish new HCPCS codes for apheresis platelets stored in platelet additive solution (PAS). PAS may offer significant safety improvements over conventional platelet products. Apheresis platelets traditionally are co-administered with donor plasma. However, donor plasma is associated with adverse patient reactions, most notably allergic and febrile reactions. Allergic reactions occur in approximately 1 in 33 to 1 in 100 transfusions. In PAS platelets, 65 percent of the donor plasma is replaced with FDA approved platelet additive solution, thereby reducing the risks and costs associated with such adverse reactions.

AABB believes there is a clear national operating need for new HCPCS codes for PAS platelets, which are clearly distinguishable from other blood components. Storing platelets in PAS is operationally and clinically different from other processing methods, such as leukocyte-reduction and irradiation, and therefore necessitates a unique HCPCS code. Absent new codes to enable appropriate billing of PAS platelets, patients may not have access to these new products.

C. *Extended Antigen-Matched Blood*

AABB encourages CMS to consider mechanisms to improve the coding and reimbursement for extended antigen-matched blood. Patients who undergo chronic blood transfusions, particularly for rare diseases such as sickle-cell anemia and thalassemia, are at an increased risk of alloimmunization. This potentially life-threatening development occurs when the recipient of a blood transfusion develops antibodies to specific red blood cell (RBC) antigens in the donor's blood. Extended antigen-matched red blood cells (RBCs) can be used to reduce the risk of alloimmunization among chronically transfused patients.

Finding the correct blood for a patient with a rare antigen profile can be complicated, and may involve a national search and take hours, days or weeks. Currently, antigen tested blood is coded through a collection of codes, including a code for leukocyte reduced RBCs and separate antigen testing codes. We urge CMS to consider (1) revising the P-codes for leukocyte reduced RBCs to reflect the extent of antigen-matching performed on the blood or (2) ensuring that CPT codes for blood typing, such as 85905 (Blood typing, serologic, RBC antigens, other than ABO or Rh) (D) each), are assigned a status indicator ensuring separate APC payment for performing these services.

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AABB commends CMS for soliciting stakeholder feedback on the HCPCS codes for blood products. We believe that the feedback CMS receives in response to this solicitation is an important first step for updating the codes. In addition, we believe that a deliberative, cooperative process is necessary to ensure the new HCPCS code descriptors provide patients with increased access to new technologies and new blood products, and achieve more consistent and accurate billing practices for blood products. Thus, we encourage CMS to convene stakeholders for a collaborative workshop prior to establishing, finalizing or implementing a thoroughly revised code set for blood products.

If you have any questions or need addition information, please contact Leah Stone, Director, Public Policy and Advocacy at 301-215-6554 or lmstone@aabb.org.

Sincerely,

Miriam A. Markowitz
Chief Executive Officer