



Advancing Transfusion and
Cellular Therapies Worldwide

September 8, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (CMS-1678-P)

Dear Administrator Verma:

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 (OPPS) that was published in the *Federal Register* on July 20, 2017.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

AABB commends CMS for continuing to provide separate payments for blood products in the hospital outpatient setting, but encourages CMS to ensure that the proposed payment rates for blood products are adequate.

AABB appreciates that CMS will continue to provide separate payments for blood products in the outpatient setting. These distinct payments recognize the important role blood and individual blood products play in caring for a wide range of patients. They also are needed to account for the increasing cost of critical blood safety measures provided by non-profit blood centers. We urge CMS to maintain its policy of providing separate APC payments for blood products in 2018 and future years.

4550 Montgomery Avenue
Suite 700, North Tower
Bethesda, MD 20814-3304
+ 1 301.907.6977 MAIN
+ 1 301.907.6895 FAX
www.aabb.org

As hospitals and blood centers face economic challenges, it is important that Medicare and other payers establish appropriate payment policies and adequate reimbursement rates for blood products. This will help ensure that patients continue to have access to safe, clinically effective blood components. AABB commends CMS for proposing to increase reimbursement for several blood products, including but not limited to platelets (e.g., P9019). However, AABB is concerned about CMS' proposal to reduce reimbursement rates for many blood products.

As AABB and others in the transfusion medicine community have previously indicated, APC payment rates for blood products lag behind their actual costs and fail to account for safety advances in a timely manner. These payments typically are below the amounts hospitals pay blood centers for individual products and furthermore do not provide for additional hospital overhead costs. For instance, AABB is concerned that CMS' proposed payment rates for cryoprecipitate (P9012) and solvent/detergent treated pooled frozen plasma (P9023) are inadequate and do not cover the costs of the products. As another example, AABB encourages CMS to reevaluate its proposed payment rate for CMV-negative leukoreduced pheresis platelets (P9055) to ensure that reimbursement is adequate in all regions throughout the country. AABB is concerned that the proposed payment rate is inadequate and reflects wide regional variation of utilization. In addition, AABB recommends that CMS reassess the proposed payment reduction for leukoreduced apheresis platelets (P9035), since the product is frequently transfused.

Similarly, AABB requests that CMS reevaluate the proposed payment rate for pooled pathogen reduced plasma (P9070), as the proposed reimbursement rate does not reflect the cost of the product. AABB recognizes that the code was introduced in 2016, and therefore the hospital cost data is limited. The information reported to CMS may not accurately reflect the use of the product due to potential erroneous coding and limitations of blood bank information systems, which may have delayed the implementation of proper coding for the product.

AABB requests that CMS consider potential alternative methodologies for setting APC payment rates for blood products, seeking input from affected stakeholders. AABB would welcome the opportunity to work with CMS and other interested parties to determine the most appropriate payment methodology to allow for timely implementation of blood safety measures and availability of blood products.

AABB urges CMS to ensure that payment rates are adequate for allogeneic transplantation of hematopoietic progenitor cells per donor (CPT code 38240) and to retain the status indicator "B" for CPT code 38205.

AABB commends CMS for using the logic finalized in the CY 2017 hospital outpatient payment rule to update the payment rate for allogeneic transplantation of hematopoietic progenitor cells per donor (CPT code 38240). Although AABB encourages CMS to continue using this logic to calculate the payment rate for code 38240, we are concerned that the proposed payment rate for 2018 is artificially low due to potential miscoding or underreporting by facilities. The low payment rate is especially problematic since donor costs continue to rise. We encourage CMS to ensure that payment rates are adequate so that patients continue to have

access to allogeneic transplantation of hematopoietic progenitor cells in the hospital outpatient setting.

Additionally, AABB appreciates CMS' attempt to create uniformity in status indicators among a family of codes. However, 38205 is a code that applies to harvesting cells from a donor for intended use in a patient, in this case a Medicare beneficiary. CMS' billing guidance instructs facilities to hold donor charges and submit them on the patient's transplant bill. Therefore, CMS' proposal to change the status indicator for 38205 from "B" to "S" could accidentally encourage facilities to incorrectly submit for payment at the time of donor cell harvest. Thus, we encourage CMS to maintain the current status indicator of "B" for code 38205.

AABB encourages CMS to reduce unnecessary burdens for clinicians and providers by revising the HCPCS p-code descriptors for blood products.

AABB recommends that CMS consider reducing unnecessary burdens for clinicians and providers by revising the HCPCS p-code descriptors for blood and blood products. In the proposed rule updating hospital outpatient payment policies for FY 2017, CMS solicited feedback regarding the current set of HCPCS p-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.

AABB urges CMS to continue its examination of the p-codes for blood products by convening stakeholders for a public meeting or collaborative workshop prior to establishing, finalizing, or implementing a thoroughly revised code set for blood products. We believe that the code set should align with current clinical practice, manufacturers' needs, and the introduction of new products. In addition, we encourage CMS consider the following specific recommendations:

- (1) Retain unique HCPCS codes for each different blood product based on processing method, since these methods result in blood products that are distinguishable and used for distinct purposes.
- (2) Establish a mechanism to immediately begin billing for a new blood product or a new technology that is not captured by existing p-codes by establishing a "not otherwise classified" code for blood products. In 2013, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) 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.
- (3) Revise the consistency and uniformity of the descriptors used for blood products, change the order of the products in the code set to ensure that codes involving the same category of blood (i.e., plasma, platelets, and red blood cells) are listed in

consecutive order, and modify the descriptors and codes for certain products to reflect current clinical practice and manufacturing processes.

AABB would welcome the opportunity to work closely with CMS on a collaborative effort to revise the HCPCS code set for blood products.

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

Sincerely,

Zbigniew M. Szczepiorkowski, MD, PhD, FCAP
President
AABB